
June 2011**INFLUENZA
PANDEMIC**

**Lessons from the
H1N1 Pandemic
Should Be
Incorporated into
Future Planning**



Highlights of [GAO-11-632](#), a report to congressional requesters

Why GAO Did This Study

The 2009 H1N1 influenza pandemic was the first human pandemic in over four decades, and the Centers for Disease Control and Prevention (CDC) estimate that there were as many as 89 million U.S. cases. Over \$6 billion was available for the response, led by the Departments of Health and Human Services (HHS) and Homeland Security (DHS), with coordination provided by the Homeland Security Council (HSC) through its National Security Staff (NSS). In particular, HHS's CDC worked with states and localities to communicate with the public and to distribute H1N1 vaccine and supplies.

GAO was asked (1) how HHS used the funding, (2) the key issues raised by the federal response, and (3) the actions taken to identify and incorporate lessons learned. GAO reviewed documents and interviewed officials from five states about their interaction with the federal government. GAO also reviewed documents and interviewed officials from HHS, DHS, the Department of Labor's Occupational Safety and Health Administration (OSHA), NSS, and others, such as associations.

What GAO Recommends

GAO recommends that the HSC direct the NSS, in concert with HHS and DHS, to incorporate lessons from the H1N1 pandemic into future planning and share these lessons with key stakeholders. NSS agreed to take the recommendations under advisement. HHS, DHS, and OSHA provided comments and generally agreed with our findings.

View [GAO-11-632](#) or key components. For more information, contact Bernice Steinhardt at (202) 512-6543 or steinhardtb@gao.gov or Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

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INFLUENZA PANDEMIC

Lessons from the H1N1 Pandemic Should Be Incorporated into Future Planning

What GAO Found

As of December 2010, HHS had spent about two-thirds of the \$6.15 billion that it had available for the H1N1 pandemic response. HHS spent the majority of the funds on developing and purchasing H1N1 vaccine and providing grants to all the states and selected local jurisdictions. State and local health officials reported that the grant funding was critical to their response efforts but also noted challenges presented by the grants' administrative requirements. HHS's spending plans for the remaining \$1.98 billion include longer-term pandemic preparation efforts, such as activities to reduce the length of time required to produce a vaccine.

Several key issues were raised by the federal government's response to the H1N1 pandemic.

- Prior pandemic planning efforts and federal funding paid off, although specific aspects of prior planning were not relied on because of the nature of the H1N1 pandemic. For example, interagency meetings and exercises built relationships that were valuable during the response. Prior funding built capacity in several areas, including vaccine production.
- The credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials. However, state and local jurisdictions valued the flexibility that they had in deciding their distribution methods. Additionally, while the use of a central distributor for the vaccines was generally cited as an effective practice, the 100-dose minimum order was viewed to be problematic.
- Public surveys generally found CDC's communication efforts to be successful in reaching a range of audiences; however, these messages fell short in meeting the needs of some non-English-speaking populations.
- Deployment of the Strategic National Stockpile—a supply of medicines and medical supplies to be used for a national emergency—met the established goal. However, CDC and state officials identified gaps in planning, including disparities between the materials expected and those delivered, as well as the need for long-term storage plans for stockpile materials.

The NSS asked federal agencies—including HHS and DHS—to complete after-action reports based on their involvement in the pandemic response. The NSS has not determined if these reports—and the associated lessons learned—will be shared with key stakeholders. Nevertheless, a DHS official commented that sharing lessons from the reports with key stakeholders would foster a spirit of government transparency and might help build stakeholder trust.

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Abbreviations

ACIP	Advisory Committee on Immunization Practices
ASPR	Office of the Assistant Secretary for Preparedness and Response
ASTHO	Association of State and Territorial Health Officials
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
EUA	emergency use authorization
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HSC	Homeland Security Council
IOM	Institute of Medicine
NACCHO	National Association of County and City Health Officials
NSS	National Security Staff
OSHA	Occupational Safety and Health Administration
PHER	Public Health Emergency Response
SNS	Strategic National Stockpile
WHO	World Health Organization

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June 27, 2011

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Roy Blunt
United States Senate

The Honorable Joe Barton
House of Representatives

In response to the global spread of the H1N1 influenza virus, the United Nations' World Health Organization (WHO)¹ declared the first human influenza pandemic in more than four decades on June 11, 2009.² Prior to this declaration, H1N1 influenza had spread across the United States after first being detected in California in April 2009.³ The Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) estimated that there were as many as 89 million U.S. cases of H1N1

¹As part of its overall mission to protect public health, this international entity monitors global influenza outbreaks and declares pandemics based on the pattern of outbreaks in its regions.

²Influenza pandemics occur when a new influenza virus emerges and spreads around the world, and most people do not have immunity. This definition is based on spread of the disease, not severity. Three pandemics occurred in the 20th century: the “Spanish flu” of 1918, which caused 500,000 deaths in the United States; the “Asian flu” of 1957, which caused 70,000 deaths in the United States; and the “Hong Kong flu” of 1968, which caused 34,000 deaths in the United States.

³Throughout this report, we use “H1N1 influenza” to refer to the 2009 H1N1 influenza. We also use “H1N1 pandemic” to refer to the 2009 H1N1 influenza pandemic.

influenza from April 2009 to April 2010.⁴ CDC estimated that these cases led to as many as 403,000 hospitalizations and 18,300 deaths during that period, with a disproportionate number of children affected as compared to typical influenza seasons. WHO declared that the 2009 H1N1 influenza pandemic ended on August 10, 2010.

Prior to the H1N1 pandemic, federal, state, and local governments were involved in national pandemic planning and preparedness activities. At the federal level these activities—which were largely coordinated by the Homeland Security Council (HSC)⁵—included releasing a national pandemic strategy and a national pandemic implementation plan in 2005 and 2006, respectively, and holding regular interagency meetings. Additionally, as part of pandemic planning, HHS funded the development of medical countermeasures, such as vaccines and antiviral drugs.⁶ The national pandemic strategy and the national pandemic implementation plan designated HHS and the Department of Homeland Security (DHS) as the two agencies that would lead a federal response to an influenza pandemic. However, because these planning and preparedness activities were geared toward responding to an avian influenza pandemic that originated overseas and had a higher fatality rate, some adjustments during the H1N1 pandemic response were necessary. Accordingly, the National Security Staff (NSS), which supports the HSC, developed an

⁴See Centers for Disease Control and Prevention, “Updated CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations, and Deaths in the United States, April 2009 – April 10, 2010,” http://www.flu.gov/individualfamily/about/h1n1/estimates_2009_h1n1.html (accessed Dec. 7, 2010).

⁵The HSC was established pursuant to Executive Order 13228, on October 8, 2001, for purposes of advising and assisting the President with respect to all aspects of homeland security and serving as a mechanism for ensuring (1) coordination of homeland security-related activities of executive departments and agencies and (2) effective development and implementation of homeland security policies. The Congress subsequently established the HSC for the purpose of more effectively coordinating the policies and functions of the federal government relating to homeland security. See Homeland Security Act of 2002, Pub. L. No. 107-296 (Nov. 25, 2002), 6 U.S.C. § 491 and § 494.

⁶Medical countermeasures are medications, biological products, or devices that treat, identify, or prevent harm from a biological or other agent that may cause a public health emergency. Medical countermeasures for use during an influenza pandemic may include vaccines, antiviral drugs, personal respirators, and influenza diagnostic tests. Vaccine, considered the first line of defense against influenza, is used to stimulate the production of an immune system response to protect the body from disease. Antiviral drugs are medications that can prevent or reduce the severity of a viral infection, such as influenza.

additional document, the *National Framework for 2009-H1N1 Influenza Preparedness and Response*.⁷

To aid in the response to the H1N1 pandemic, the federal government took a variety of measures. The Congress appropriated funds to HHS specifically to prepare for and respond to an influenza pandemic as part of a supplemental appropriation in June 2009.⁸ The federal government—and particularly CDC—collaborated with state and local jurisdictions,⁹ professional associations, and private health care providers, among others, to take a variety of measures to mitigate the spread of disease, such as communicating with the public, distributing vaccines, conducting surveillance, and distributing items from the Strategic National Stockpile (SNS).¹⁰

Because of the possibility of another influenza pandemic and our prior work on pandemic preparedness,¹¹ you asked us to examine the lessons learned from the federal response to the H1N1 pandemic and identify how the federal government is incorporating these lessons into future pandemic planning. As agreed, this report examines (1) how HHS used 2009 supplemental funding to respond to the H1N1 pandemic, (2) the key issues raised by the federal government's response to the H1N1 pandemic, and (3) the actions that federal agencies are taking to identify and

⁷On May 26, 2009, the President established the NSS, under the direction of the National Security Advisor, to integrate White House staff supporting national security and homeland security. The President stated that the NSS would support the HSC, and that the HSC would be maintained as the principal venue for interagency deliberations on issues that affect the security of the homeland, such as pandemic influenza. See *Statement by the President on the White House Organization for Homeland Security and Counterterrorism*, http://www.whitehouse.gov/the_press_office/Statement-by-the-President-on-the-White-House-Organization-for-Homeland-Security-and-Counterterrorism(accessed May 9, 2011).

⁸Supplemental Appropriations Act, 2009, Pub. L. No. 111-32, 123 Stat. 1859, 1884-1886 (June 24, 2009). A supplemental appropriation is an act appropriating funds in addition to those already enacted in the annual appropriation act. Supplemental appropriations provide additional budget authority usually in cases where the need for funds is too urgent to be postponed until enactment of the regular appropriation bill.

⁹For this report, we use “states and local jurisdictions” to refer to state, local, and tribal governments, as well as territorial and insular areas.

¹⁰The SNS, managed by CDC, contains large quantities of medicine and medical supplies intended to protect and treat the public if there is a public health emergency that is severe enough that local supplies may be exhausted.

¹¹Related products are listed at the end of this report.

incorporate lessons learned from the issues that arose from the H1N1 pandemic into planning.

To examine how HHS used the 2009 supplemental funding to respond to the H1N1 pandemic, we reviewed the Supplemental Appropriations Act, 2009; HHS's reports to the Congress detailing the ways that HHS spent funds; and HHS's amended spending plans that were also submitted to the Congress.¹² To determine the reliability of the data in these reports, we reviewed the reports for internal consistency and resolved questions with appropriate HHS officials; we did not independently verify the information provided in these reports. We believe that the data are sufficiently reliable for our purposes. While HHS used funds from other appropriations in the H1N1 pandemic response effort, we focused our review on the \$6.15 billion available to HHS that was provided through the 2009 supplemental appropriation. Because this appropriation required that a portion of the supplemental funds be directed toward upgrading state and local public health capacity, we reviewed requirements of the grants that were awarded to state and local jurisdictions for this purpose. To examine how state and local jurisdictions used the grant funds, we reviewed documents and interviewed officials from CDC's Division of State and Local Readiness, the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO). We also interviewed officials involved in the H1N1 pandemic response in a sample of five states—Georgia, Nebraska, Texas, Vermont, and Washington—to learn about how their jurisdictions used the response funds. We chose these states to provide insight into the experiences of a range of states; however, their experiences are not generalizable to all 50 states. We selected states that reflected a range of key characteristics, including when the state first reported experiencing widespread H1N1 influenza activity, interim state-specific H1N1 vaccination rates among the initial target groups for the H1N1 vaccine, population in 2008, census region, total grant amount awarded to the state for the H1N1 pandemic response, and the state's public health structure. Appendix I includes information on the five selected states. In general, within each state, we spoke with officials from the governor's office, the state health agency, the

¹²To measure spending, we reviewed the department's obligations. "Obligation" refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future. Agencies incur obligations, for example, when they award grants or contracts.

state emergency management agency, and the state education agency.¹³ In addition, to provide an example of how the territories and insular areas used pandemic grant funds, we contacted officials from the U.S. Virgin Islands based on the same criteria that we used to select the states in our sample.

To examine the key issues raised by the federal government's response to the H1N1 pandemic, we focused on the actions of HHS and DHS because they share federal leadership responsibilities for pandemic influenza response. Within HHS, we reviewed documents and interviewed officials from the Office of the Assistant Secretary for Preparedness and Response (ASPR), ASPR's Biomedical Advanced Research and Development Authority (BARDA), the Food and Drug Administration (FDA), and CDC. Within DHS, we reviewed documents and interviewed officials from the Office of Health Affairs, Directorate for Management, Office of Operations Coordination, and Federal Emergency Management Agency. Because of their respective roles in the H1N1 pandemic response, we also reviewed documents and interviewed officials from the Department of Education's (Education) Office of Safe and Drug Free Schools regarding school closure policies and the Department of Labor's Occupational Safety and Health Administration (OSHA) regarding guidance on the use of personal protective equipment and the protection of workers' safety and health.¹⁴ To learn about the federal government's interaction with state and local jurisdictions, we interviewed officials from the same judgmental sample of five states. We also reviewed reports and interviewed officials from the U.S. Virgin Islands, ASTHO, NACCHO, the National Governors Association, the Center for Infectious Disease Research and Policy, the Association of Immunization Managers, the Institute of Medicine (IOM), and the National Indian Health Board.¹⁵

¹³In states without a centralized public health structure, we also met with at least one local jurisdiction's health department.

¹⁴"Personal protective equipment" encompasses the specialized clothing and equipment worn by workers for protection against health and safety hazards. For health care personnel, personal protective equipment may include respirators, face masks, gloves, eye protection, face shields, gowns, and head and shoe coverings.

¹⁵The Center for Infectious Disease Research and Policy addresses public health preparedness and emerging infectious diseases response. The Association of Immunization Managers represents state, local, and territorial immunization program managers. The National Indian Health Board represents tribal governments—both those operating their own health care delivery systems through contracting and compacting and those receiving health care directly from the Indian Health Service.

To examine the actions that federal agencies are taking to identify and incorporate lessons learned from the issues that arose from the H1N1 pandemic into planning, we interviewed officials and reviewed documents from HHS, DHS, Education, and the Department of Labor. We interviewed officials from the NSS, which was responsible for developing the *National Framework for 2009-H1N1 Influenza Preparedness Response* and for holding interagency coordination meetings during the H1N1 pandemic response. We also examined the *National Response Framework*—a guide for the federal government to use in responding to domestic incidents—which specifies that evaluation and continual process improvement are cornerstones of effective preparedness. The framework notes that improvement planning should develop specific recommendations for changes in practice, timelines for implementation, and assignments for completion.¹⁶

We conducted this performance audit from April 2010 to June 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Pandemic Preparedness Prior to the H1N1 Pandemic

The emergence of H5N1 avian influenza (also known as avian influenza or bird flu) in Asia in 2003 raised concerns among experts that it or another influenza virus might significantly mutate, resulting in a human influenza pandemic. This led to the development of the national pandemic strategy

¹⁶Department of Homeland Security, *National Response Framework* (Washington, D.C., January 2008), 32.

and national pandemic implementation plan.¹⁷ This strategy and plan established that the Secretary of Health and Human Services is to lead the federal public health and medical response to a pandemic and the Secretary of Homeland Security is to lead the overall domestic incident management and federal coordination.

Additionally, prior to the H1N1 pandemic, the Congress appropriated funds to support the federal government's influenza pandemic preparedness and improve related state and local public health capabilities. In fiscal year 2006, the Congress appropriated about \$5.60 billion to HHS through supplemental appropriations to support pandemic preparedness and response efforts, such as vaccine and antiviral drug development and stockpiling, state and local preparedness, and international collaboration.¹⁸ HHS reported spending more than half of the funds (about \$3.10 billion) on activities related to vaccine development, stockpiling, and infrastructure improvement. For example, the department awarded contracts to two domestic influenza vaccine manufacturers to retrofit their facilities—that is, to upgrade existing facilities to optimize and enhance their ability to produce influenza vaccines. HHS spent nearly a quarter of the funds (about \$1.30 billion) on activities related to developing and stockpiling antiviral drugs. For example, the department completed the purchase of 50 million courses of antiviral drugs for the SNS and provided funding to states to increase state stockpiles as part of its goal of ensuring the availability of antiviral drug treatment courses for 25 percent of the U.S. population in case of an influenza pandemic.¹⁹ HHS invested in the development of Peramivir, an intravenously administered

¹⁷The *National Strategy for Pandemic Influenza* (national pandemic strategy), released in 2005, provides a framework for planning efforts for how the country will prepare for, detect, and respond to an influenza pandemic. The strategy reflects the federal government's approach to the pandemic threat and is based on three pillars: (1) preparedness and communication, (2) surveillance and detection, and (3) response and containment. The *National Strategy for Pandemic Influenza Implementation Plan* (national pandemic implementation plan) published in 2006, further clarifies the roles and responsibilities of federal and nonfederal entities—including state, local, and tribal governments; the private sector; international partners; and individuals—to prepare themselves and their communities. The national pandemic implementation plan includes 324 action items to address the threat of a pandemic, most of which have been reported as completed.

¹⁸Pub. L. No. 109-148, 119 Stat. 2680, 2783, 2786 (Dec. 30, 2005), and Pub. L. No. 109-234, 120 Stat. 418, 479-80 (June 15, 2006).

¹⁹The federal stockpile of antiviral drugs includes oral formulations (Tamiflu), inhaler formulations (Relenza), and doses for pediatric patients.

antiviral drug for seriously ill patients with influenza. HHS also funded the development and clinical trials of influenza diagnostic testing devices that allow for the diagnosis of influenza in a variety of settings.²⁰

2009 H1N1 Pandemic

The first case of H1N1 influenza was detected in the United States on April 15, 2009. Cases of H1N1 influenza first appeared in California and Texas, and soon spread across the country and around the world. (See fig. 1 for a timeline of key events.) At the same time, an outbreak of H1N1 influenza was occurring in Mexico. In response, the NSS developed the *National Framework for 2009-H1N1 Influenza Preparedness and Response* as a tool to guide the federal response efforts.²¹ The framework was built on the existing national pandemic strategy and national pandemic implementation plan and contained four pillars for the response: surveillance, mitigation measures, vaccination, and communication and education.

²⁰For a more detailed discussion of how the 2006 supplemental funds were spent for pandemic preparedness, see GAO, *Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts*, GAO-09-334 (Washington, D.C.: Feb. 26, 2009), 30.

²¹According to HHS officials, they received this document from the NSS in July 2009.

Figure 1: Key Events Related to the H1N1 Influenza Pandemic in the United States, April 2009 through August 2010

Interactive features:

Roll your mouse over each month to see the result
For a printable copy of this figure, see appendix II



Sources: GAO analysis; James Gathany, Cade Martin (photos).

Notes: The declaration of a public health emergency, pursuant to 42 U.S.C. § 247d, provided the basis for the Secretary of Health and Human Services to exercise the authority under certain circumstances to approve the emergency use of unapproved drugs, devices, or biological products (or the emergency use of approved drugs, devices, or biological products for unapproved uses) through emergency use authorizations. 21 U.S.C. § 360bbb-3.

The President's declaration of a national emergency pursuant to the National Emergencies Act provided the Secretary of Health and Human Services the authority to temporarily waive or modify certain requirements affecting the health care system throughout the duration of the public health emergency. 50 U.S.C. §§ 1621 and 1631; 42 U.S.C. § 1320b-5.

The release of 25 percent of the influenza supplies from the Strategic National Stockpile included antiviral drugs and equipment to protect against influenza transmission, such as face masks, respirators, gowns, and gloves.

The H1N1 pandemic occurred in two waves in the United States.²² The first wave occurred during spring 2009 and the second wave during fall 2009, with H1N1 influenza activity peaking in October 2009, based on the number of new cases. A greater proportion of children and young adults, as well as pregnant women, were adversely affected by the H1N1 influenza virus as compared to the typical influenza season.

H1N1 Vaccine Production and Distribution

When the H1N1 influenza outbreak occurred in April 2009, HHS began working to isolate the H1N1 influenza strain and worked with five vaccine manufacturers to develop a 2009 H1N1 influenza vaccine (H1N1 vaccine) to protect the public against H1N1 influenza.²³ The H1N1 vaccines were manufactured using the same methods that these manufacturers used for seasonal influenza vaccine production.

In anticipation of the availability of the H1N1 vaccine and the possibility that initial supply might not meet demand for the vaccine, in July 2009, CDC's Advisory Committee on Immunization Practices (ACIP) issued recommendations for the target groups for the H1N1 vaccine.²⁴ These five target groups, comprising about 159 million persons, were recommended

²²Influenza pandemics can have successive waves of disease and last for up to 3 years.

²³Specifically, FDA determined that a monovalent influenza vaccine, which protects against a single strain of influenza, manufactured according to the same process as licensed seasonal influenza vaccines—but formulated to contain the pandemic 2009 H1N1 influenza virus strain antigen—could be approved as a strain change supplement to existing licensed influenza vaccines. An antigen is the active substance in a vaccine that provides immunity by causing the body to produce protective antibodies to fight off a particular influenza strain. To be effective, an influenza vaccine must be created to match a specific influenza strain because influenza strains undergo minor genetic changes from year to year. The 2009 H1N1 influenza vaccine was separate from, and in addition to, the seasonal influenza vaccine for the 2009-2010 influenza season. In addition, manufacturers and the National Institutes of Health conducted clinical trials to determine the optimal dosage and number of doses that would be required to generate an immune response to 2009 H1N1 infection.

²⁴Centers for Disease Control and Prevention, "Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)," *Morbidity and Mortality Weekly Report*, vol. 58, no. RR-10 (August 2009), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm> (accessed Apr. 25, 2011). ACIP develops written recommendations for the routine administration of vaccines to children and adults in the civilian population. These recommendations include age for vaccine administration, number of doses and dosing interval, and precautions and contraindications.

to be first to receive the H1N1 vaccine.²⁵ ACIP also identified a subset of the initial target groups, comprising about 42 million persons, to whom providers should give priority if H1N1 vaccine availability was too limited to initiate vaccination for all people in the five initial target groups.²⁶ However, at the time it made the recommendations, ACIP did not predict that there would be a need to limit vaccine to the subset of the target groups in most areas of the country.

Unlike seasonal influenza vaccine, which is largely purchased by the private sector, the federal government purchased all of the H1N1 vaccine licensed for use in the United States. HHS allocated doses to each state for distribution based on the overall population of the state. The states, in turn, placed orders for their allocated doses and determined which providers should receive the vaccine. CDC estimated that from October 2009 through May 2010, 27 percent of the U.S. population over the age of 6 months (about 81 million people) was vaccinated against H1N1 influenza, including about 34 percent of individuals in the initial target groups.²⁷

Strategic National Stockpile

In addition to the production and distribution of the H1N1 vaccine, another federal action in response to the H1N1 pandemic was the deployment of influenza response supplies from the SNS. The SNS, managed by CDC, contains large quantities of medicine and medical supplies intended to protect and treat the public if there is a public health emergency that is severe enough that local supplies may be exhausted. Each state has plans to receive materials from the SNS and distribute them to local communities as quickly as possible. The H1N1 pandemic marked

²⁵These recommendations, based on the epidemiology of H1N1 influenza and projected vaccine supply, were made to assist in planning and to alert providers and the public about who should be first to receive the vaccine. ACIP recommended the following five initial target groups: pregnant women, household contacts and caregivers for children younger than 6 months of age, health care and emergency services personnel, individuals from 6 months through age 24, and persons aged 25 through 64 with health conditions associated with higher risk of medical complications from influenza.

²⁶The subset of the target groups included pregnant women, individuals living with or caring for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, and children aged 6 months through 4 years or aged 5 through 18 years with chronic medical conditions.

²⁷Centers for Disease Control and Prevention, “Final Estimates for 2009-10 Seasonal Influenza and Influenza A 2009 (H1N1) Monovalent Vaccination Coverage – United States, August 2009 through May 2010,” http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm (accessed Oct. 8, 2010).

the largest deployment of materials from the SNS to date in an emergency situation, according to CDC.

HHS Funded a Range of Pandemic Influenza Activities with Supplemental Funds

Most Supplemental Funds Were Spent on Vaccine Purchase and Support of State and Local Pandemic Response Efforts

The Congress Appropriated Funds to HHS to Meet the Threat of Pandemic Influenza

HHS had \$6.15 billion available from the 2009 supplemental appropriation to spend on pandemic influenza activities. Specifically, the Congress appropriated \$1.85 billion immediately to HHS in June 2009, shortly after WHO declared the start of the pandemic. The Congress also appropriated up to \$5.80 billion in additional contingent funding. These contingent funds would only be available in the amounts designated by the President, in written notices to the Congress, as emergency funds required to address critical needs related to emerging influenza viruses. In July and September of 2009, the President notified the Congress of the need for additional funding, and accordingly, \$4.54 billion of the contingent funds became available to HHS. From this \$4.54 billion, HHS transferred about \$241 million to other departments, which left about \$4.30 billion available for HHS.²⁸ As of December 2010, the remaining \$1.259 billion from the contingent fund was not designated by the President as required to address critical needs related to emerging influenza viruses; however,

²⁸HHS reported that it transferred about \$241.20 million to the Department of Defense, Department of Veterans Affairs, Department of State, and Department of Agriculture. Since HHS spent the majority of the 2009 supplemental appropriation, we did not determine how the \$241 million transferred to these other departments was spent by them. We did not independently verify the amount of money that was transferred. The 2009 supplemental appropriation requires that all funds transferred to these other departments go toward purposes related to preparing for or responding to an influenza pandemic.

HHS Has Spent Almost 70 Percent of Available Supplemental Funds

these funds were rescinded under the fiscal year 2011 continuing appropriations act.²⁹

From June 2009 through December 2010, HHS spent about \$4.17 billion (about two-thirds)³⁰ of the \$6.15 billion that it had available from the 2009 supplemental appropriation, according to HHS's report to the Congress on pandemic influenza preparedness spending.³¹ Of the \$4.17 billion spent by HHS, about \$1.72 billion (41 percent) was spent on vaccine production, which includes the purchase of H1N1 vaccine from five influenza vaccine manufacturers, adjuvants,³² and ancillary supplies, such as needles and syringes, distributed along with the H1N1 vaccine. Specifically, HHS funded the development of and purchased over 190 million doses of the H1N1 vaccine and purchased 200 million ancillary supply kits.³³

Of the \$4.17 billion spent by HHS, about \$1.49 billion (36 percent) was spent on supporting state and local jurisdictions' response to the H1N1 pandemic. The majority of these funds were provided to the states through Public Health Emergency Response (PHER) grants.³⁴ The PHER grant

²⁹Section 1826 of the Department of Defense and Full-Year Continuing Appropriations Act, 2011, rescinded \$1.259 billion in contingent 2009 supplemental funds that the President had not yet designated to the Congress as emergency funds. Pub. L. No. 112-10, 125 Stat. 10, 162 (Apr. 15, 2011).

³⁰To measure spending, we looked at the agency's obligations. "Obligation" refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future. Agencies incur obligations, for example, when they award grants or contracts. Because payments are typically made as goods or services are received, the funds listed may not have been expended. Upon termination of a contract, unexpended funds may be deobligated and, depending on the terms of their appropriation, may remain available to the agency.

³¹Department of Health and Human Services, *Report to Congress: December 2010 Report, Pandemic Influenza Preparedness Spending* (Washington, D.C., February 2011). We did not independently verify information on obligations provided in the report.

³²Adjuvants are substances that may be added to a vaccine to increase the body's immune response to the vaccine. While adjuvants were purchased by HHS as a precautionary measure, they were not used in the H1N1 vaccine.

³³HHS purchased over 190 million doses of vaccine. Of these doses, over 156 million were made available for distribution to the U.S. public and the Department of Defense, 17 million were distributed internationally, and the remainder were not distributed.

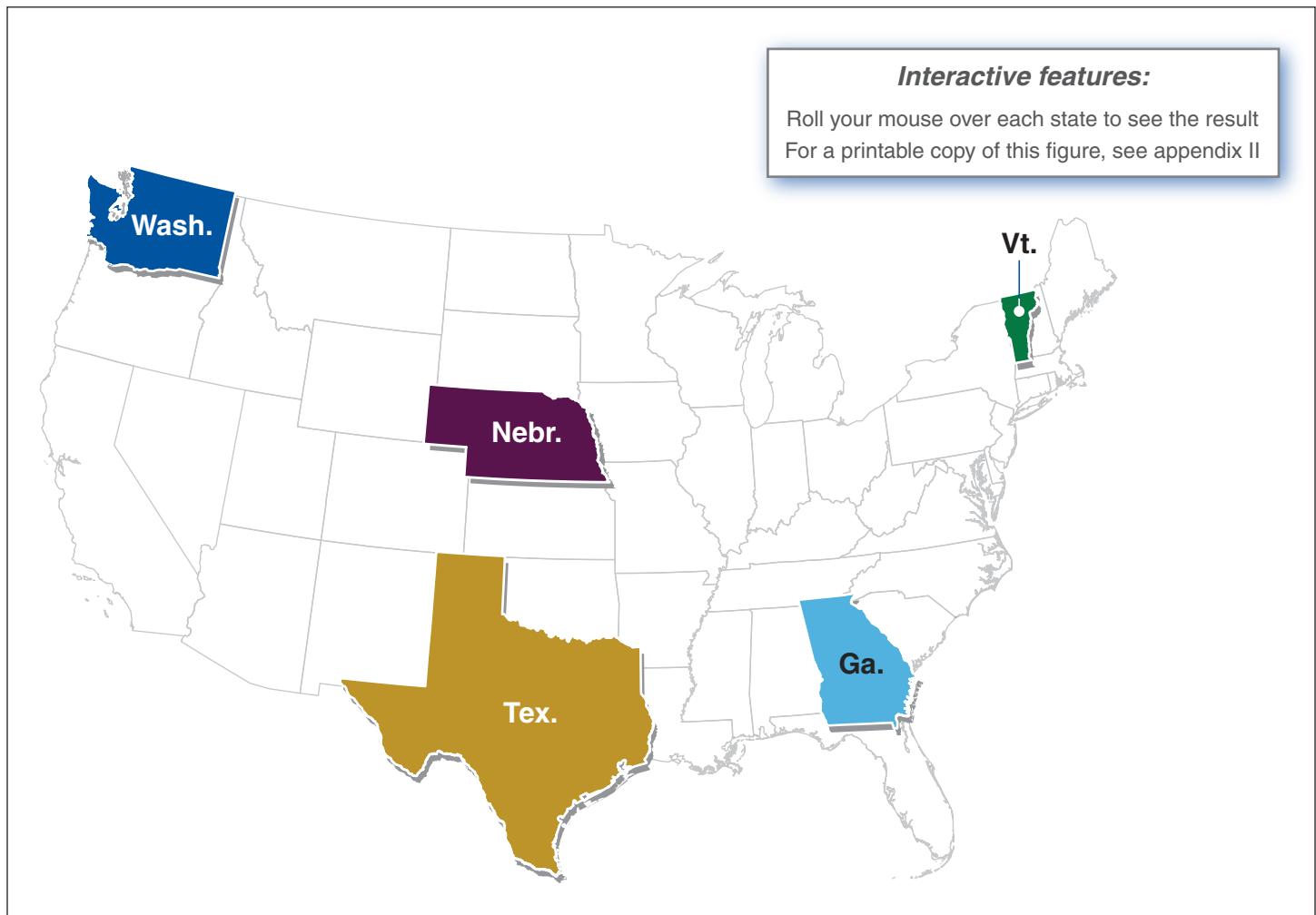
³⁴CDC awarded PHER grants to each of the 50 states; 4 local health departments (Chicago, Los Angeles County, New York City, and Washington, D.C.); and American Samoa, Guam, the Marshall Islands, Micronesia, Northern Mariana Islands, Palau, Puerto Rico, and the U.S. Virgin Islands. HHS also provided funds to hospitals, through states, as part of the Hospital Preparedness Program.

funds were distributed in four phases beginning in August 2009, with each phase of funding targeting specific focus areas, such as vaccination or communication efforts with high-risk populations.³⁵ A report by ASTHO concluded that state and local jurisdictions could not have responded as effectively to the H1N1 pandemic without the PHER grant funds, particularly given the ongoing budgetary constraints of states.³⁶ (See fig. 2 for examples of how states and local jurisdictions used the PHER grants.) HHS spent the remaining \$1 billion (24 percent) on other purposes. See table 1 for information on HHS activities supported by the 2009 supplemental appropriation.

³⁵ Specifically, the first funding phase was for state and local jurisdictions to assess their capabilities for pandemic influenza response and to address gaps in vaccination, antiviral distribution and dispensing, community mitigation, laboratory, epidemiology, and surveillance activities. The second funding phase was for state and local jurisdictions to plan for the vaccination campaign. The third funding phase was for states to implement the mass vaccination campaign. The fourth and final funding phase was for targeting special, hard-to-reach populations for vaccination.

³⁶ Association of State and Territorial Health Officials, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic* (Arlington, Va., June 2010), 25.

Figure 2: Examples of Ways That State and Local Jurisdictions Used the PHER Grants



Sources: GAO analysis of state data; Map Resources (map).

Table 1: HHS Activities Supported by the 2009 Supplemental Appropriation

Activity	Amount spent as of December 31, 2010 (in millions)	Percentage of total funds spent
Vaccine production includes purchase of H1N1 vaccine, adjuvant, ^a and ancillary supplies for the H1N1 vaccine.	\$1,719	41.3
PHER grants includes grants to state and local jurisdictions to upgrade state and local public health capacity.	1,404	33.7
CDC vaccination campaign includes contracts to support the distribution of H1N1 vaccine and ancillary supplies, H1N1 vaccine safety and effectiveness monitoring, and a communications campaign on vaccination and prevention.	340	8.2
Antiviral drugs includes the purchase of pediatric doses of antiviral drugs in response to the disproportionate effects of H1N1 influenza on children.	231	5.6
CDC domestic response includes funds for deployment of CDC staff to support investigations into the H1N1 outbreak along the borders and in the United States and production and distribution of a diagnostic test kit for H1N1 influenza.	199	4.8
Ongoing H1N1 activities includes funds to continue development of intravenous presentations of an antiviral drug for persons with influenza and a program to monitor the effects of use of H1N1 vaccine and antiviral drugs by pregnant women and the babies they bore.	95	2.3
Hospital Preparedness Program includes grants through states to hospitals for health care workforce protection and the development of plans to optimize usage of the health care system during an influenza pandemic.	90	2.2
CDC international response includes support for H1N1 influenza surveillance, laboratory and research projects in over 13 countries, and personnel support provided to WHO regional offices to handle H1N1 pandemic surge activities.	44	1.1
CDC communications includes funds for consumer behavioral research on messaging; use of a Web-based media monitoring system to assess message dissemination by the media about H1N1 influenza; support of pandemic influenza tabletop exercises involving national, regional, and local media outlets; and translation of pandemic influenza materials into various languages.	31	0.7
Countermeasure^b development and regulation at FDA includes the development, evaluation, licensure, and safety monitoring of the H1N1 vaccine, and FDA activities to facilitate the availability and safety monitoring of H1N1 diagnostic tests, personal protective equipment, and antiviral drugs.	9	0.2
Compensation includes funds used to support the administration of the Countermeasures Injury Compensation Program, which will provide compensation to individuals with injuries caused by certain countermeasures administered to diagnose, mitigate, prevent, or treat harm from specified material threats. ^c	4	0.1
ASPR deployment/operations support includes costs associated with sending ASPR staff to states and territories during the H1N1 pandemic.	1	0.0
Total	\$4,167	100.0

Source: GAO analysis of HHS data.

Notes: Numbers may not sum to totals because of rounding. The information presented in this table is based on Department of Health and Human Services, *Report to Congress: December 2010 Report, Pandemic Influenza Preparedness Spending* (Washington, D.C., February 2011). HHS is submitting biannual reports to the Congress on the 2009 supplemental appropriation. The February 2011 report covers spending through December 2010.

HHS reported that it transferred \$241 million to the Departments of Defense, Veterans Affairs, State, and Agriculture. Since HHS spent the majority of the 2009 supplemental appropriation, we did not determine how the \$241.20 million transferred to these other departments was spent by them. We did not independently verify the amount that was transferred. The 2009 supplemental appropriation requires that all funds transferred to these departments go toward purposes related to preparing for or responding to an influenza pandemic.

^aAdjuvants are substances that may be added to a vaccine to increase the body's immune response. While adjuvants were purchased by HHS as a precautionary measure, they were not used in the H1N1 vaccine.

^bMedical countermeasures are medications, biological products, or devices that treat, identify, or prevent harm from a biological or other agent that may cause a public health emergency. Medical countermeasures for use during an influenza pandemic may include vaccines, antiviral drugs, personal respirators, and influenza diagnostic tests.

^cThe Countermeasures Injury Compensation Program, administered by HHS's Health Resources and Services Administration, provides compensation for medical expenses, lost employment income, and/or death benefits for eligible individuals injured as a result of receiving certain countermeasures, such as vaccines, antiviral drugs, diagnostic tests, and personal protective equipment.

States Experienced Challenges with Grant Administration during the Pandemic Response

While the PHER grants were critical to state and local jurisdictions, officials from state and local jurisdictions reported experiencing challenges with the administrative requirements of the PHER grants.

- ASTHO reported that state officials found the need to submit multiple applications for the various phases of the grant, and the time spent waiting for approvals, to be time consuming during the response. Additionally, the different limitations on the use of funds in each phase made it difficult for states to plan and manage their response activities.³⁷
- Some of the local officials we interviewed reported that the specific spending requirements of the PHER funding were heavily weighted toward vaccination activities and that funds were neither flexible nor sufficient enough to address epidemiology and laboratory expenses.³⁸ Officials from Washington's Department of Health, for example, echoed this concern and told us that some local health jurisdictions in the state did not have enough funding for surveillance and laboratory expenses, but had more than enough designated for vaccination activities. Almost half of states applied for the last phase of funding—and 15 states received the funds—which were available in early 2010 for targeting special, hard-to-reach populations for vaccination. In most cases, the states were not eligible for these funds because they

³⁷ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 25.

³⁸National Association of County and City Health Officials, *H1N1 Policy Workshop Report* (Washington, D.C., June 2010), 5.

had sufficient funds left over from the previous three phases to conduct vaccination outreach to hard-to-reach, high-risk populations.

CDC officials who worked on the PHER grant program said they were aware of the challenges that states faced with the grant process and were working on addressing some of these challenges in preparation for the next public health emergency. To reduce the time that it takes for funding to reach the states, CDC officials identified ways to save time for various procedures, such as preparing draft grant guidance in advance of public health emergencies. Additionally, CDC officials told us that they are working with ASTHO to help states be better prepared to quickly use federal funding that might become available in an emergency situation. For example, CDC officials noted that states with independent local health jurisdictions could establish draft contracts with these local health jurisdictions so that funding could flow more quickly down to the local level. In addition to these measures, CDC officials are working with their General Counsel's office to look at any authorities that they may have to move funds through existing cooperative agreements in an emergency. CDC officials also agreed that the phases of the PHER grants were heavily weighted toward vaccination, but noted that they made that decision because of the anticipation that the vaccination campaign would be the largest component of the public health response. In August 2010, the state and local jurisdictions received a no-cost extension that allows them to spend the PHER grant funds through July 2011. CDC expects to have detailed data regarding the ways that states spent these funds after the grant program expires.

HHS Plans for Remaining Supplemental Funds Include Efforts to Prepare for Future Pandemics

When WHO declared the H1N1 pandemic over in August 2010, HHS had not spent about \$1.98 billion of the 2009 supplemental funds. Plans for the remaining funds include efforts that HHS identified to prepare for future pandemics. (See table 2 for additional information on how HHS plans to use these funds.) These longer-term preparations were primarily identified by an HHS review of public health emergency medical countermeasures.³⁹ This review found, for example, that continued, long-term investment is needed to improve domestic influenza vaccine production capacity and to

³⁹Office of the Assistant Secretary for Preparedness and Response, *The Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs* (Washington, D.C., August 2010), http://www.hhs.gov/nvpo/nvac/meetings/upcomingmeetings/korch_presentation.pdf (accessed June 21, 2011).

shorten the amount of time needed to produce an influenza vaccine during a pandemic. According to HHS's August 2010 amended spending plan, a portion of the remaining funds will be spent on efforts to reduce the length of time required to produce a pandemic vaccine.⁴⁰ Specifically, HHS planned to spend \$431 million—or 22 percent of these funds—on the development of new influenza vaccine technologies. Further, about \$50 million (3 percent) is planned for enhancing the available domestic fill and finish capacity—the final stage in the vaccine production process that places the vaccine in the appropriate delivery device—which has been cited as a bottleneck in the existing influenza vaccine production process.

Table 2: HHS's Planned Spending for Remaining Influenza Pandemic Funds from the 2009 Supplemental Appropriation, as of December 31, 2010

Primary activity	Subactivity	Amount (in millions)
Influenza vaccine production		\$758
	New vaccine production technologies includes supporting the development of new influenza vaccine technologies that would shorten vaccine production time.	431
	Centers for Innovation in Advanced Development and Manufacturing includes the support of multiuse facilities that could be used to expand influenza vaccine production capacity during a pandemic.	108
	H5N1 prepandemic vaccine storage and stability testing includes activities to enlarge the H5N1 prepandemic vaccine and antiviral drug stockpiles and conduct stability testing to determine the vaccine's shelf life.	54
	Adjuvants^a includes support for clinical tests of existing and new vaccines with adjuvants, development of regulatory guidance for adjuvants, and further research and development.	60
	Domestic fill and finish manufacturing network includes activities to develop a network of facilities with sufficient capacity to rapidly fill the vials, syringes, and sprayers required for delivery of influenza vaccine during a pandemic.	50
	Influenza vaccine potency and sterility test development includes activities to develop methods to improve and shorten the time needed for vaccine potency tests that determine the amount of antigen in a vaccine and sterility tests that ensure that a vaccine is not contaminated. ^b	30
	Vaccine seed optimization includes support of activities that would hasten and standardize the process for generating the virus strains used to manufacture influenza vaccines.	24
	H1N1 vaccine recovery project includes H1N1 vaccine storage and disposal.	1
	Egg supply includes support for a year-round egg supply that could be used to develop an influenza vaccine in a pandemic. ^c	1

⁴⁰Department of Health and Human Services, *Amended Spending Plan for 2009 Supplemental Funding*, as reported to the Congress in August 2010.

Primary activity	Subactivity	Amount (in millions)
Antiviral drugs	Antiviral drug advanced development includes funding for advanced development of Peramivir, an intravenously administered antiviral drug that was used during the H1N1 pandemic, plus other development activities at HHS.	435
Advanced development of diagnostics	Advanced development of diagnostic testing devices for influenza.	76
HHS/CDC		623
	CDC replenishment of supplies in the SNS includes supplies that are needed during an influenza pandemic.	257
	CDC base influenza activities supports a portion of CDC's fiscal year 2011 SNS and influenza activities.	225
	HHS/CDC Surveillance, Lab Capacity & Communications Activities supports the continuation and completion of activities begun in response to the H1N1 pandemic. This includes measures such as virus detection and countermeasure development.	141
National Institutes of Health	Pandemic influenza-related research activities	33
Compensation	Countermeasures Injury Compensation Program , which provides compensation for eligible individuals injured as a result of receiving certain medical countermeasures.	58
Total		\$1,983

Source: GAO analysis of HHS data.

Notes: Totals may not sum to totals because of rounding. The information presented in this table is based in part on Department of Health and Human Services, *Report to Congress: December 2010 Report, Pandemic Influenza Preparedness Spending* (Washington, D.C., February 2011), and Department of Health and Human Services, *Amended Spending Plan for 2009 Supplemental Funding*, as reported to the Congress in August 2010.

^aAdjuvants are substances that may be added to a vaccine to increase the body's immune response.

^bAn antigen is the active substance in a vaccine that provides immunity by causing the body to produce protective antibodies to fight off a particular influenza strain.

^cCurrent influenza vaccines are prepared from materials grown in chicken eggs.

Federal Response to the H1N1 Pandemic Highlighted a Number of Key Issues

Several key issues were raised by the federal government's response to the H1N1 pandemic. These relate to

- prior planning and funding,
- availability of vaccine and related plans for distribution,
- public communication, and
- the SNS.

Not All Aspects of the Existing Strategy and Plan Were Relied on, but Earlier Funding and Planning Paid Off

Elements of National Pandemic Strategy and Implementation Plan Were Not Relied on Because of the Nature of the H1N1 Pandemic

Given the specific characteristics of the H1N1 pandemic, the federal government did not rely on some aspects of the national pandemic strategy and national pandemic implementation plan, such as critical infrastructure protection and border and trade measures. The national pandemic strategy and national pandemic implementation plan were based on a scenario of a severe 1918-like pandemic, as well as the existing threat that an avian influenza strain, originating overseas, would cause the next pandemic. During the early months of the H1N1 outbreak, officials from DHS and other departments reported that the action items in the national pandemic implementation plan for which their respective departments had responsibility—such as border and trade measures—were not relevant for the H1N1 outbreak, and therefore were not activated.⁴¹ Federal officials noted, however, that while these actions were not taken in the H1N1 pandemic response, they could be important in a future pandemic with different characteristics, such as if there is a severe pandemic that affects critical infrastructure.⁴²

Another aspect of the national pandemic strategy and national pandemic implementation plan that was not fully tested was the shared leadership roles and responsibilities for both HHS and DHS in responding to an influenza pandemic. We previously reported that it was unclear how this shared leadership would work in practice. Under the national pandemic strategy and national pandemic implementation plan, both departments share leadership responsibilities—HHS to manage the federal public health and medical response and DHS to lead domestic incident management and federal coordination. As a result, we recommended that HHS and DHS work together to develop and conduct rigorous testing, training, and exercising for pandemic influenza to ensure that the federal leadership roles are clearly defined and understood and that leaders are

⁴¹GAO, *Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement*, GAO-10-73 (Washington, D.C.: Nov. 24, 2009).

⁴²For more information, see GAO, *Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination*, GAO-08-36 (Washington, D.C.: Oct. 31, 2007).

able to effectively execute shared responsibilities.⁴³ HHS officials told us that they are planning to exercise these roles with DHS.

The shared leadership roles between HHS and DHS were not fully implemented during this pandemic. Officials from both HHS and DHS told us that once it became clear that the H1N1 pandemic required primarily a public health response, HHS was responsible for most of the key activities.⁴⁴ Nevertheless, some state officials cited concerns about the shared federal leadership roles in the early days of the pandemic response. Specifically, officials we interviewed in four of the five states said that during that period, HHS and DHS did not effectively coordinate their release of information to their state contacts. As a result, state officials reported receiving large volumes of information—often through multiple daily conference calls or via e-mail—from both federal agencies. The amount of information—which was sometimes the same information and sometimes inconsistent—was overwhelming, according to these state officials. For example, representatives from the Georgia Emergency Management Agency told us that at one point DHS officials were telling states that confirmation of H1N1 influenza cases needed to be completed by a laboratory, which was the initial CDC guidance, while HHS officials were telling states they could confirm H1N1 cases by laboratories or an analysis of symptoms that the patient was experiencing, which was the revised CDC guidance at the end of August 2009. Officials in Vermont, Washington, and Georgia told us that over time it appeared to them that HHS—and primarily HHS’s CDC—took the lead in communicating about H1N1 and, accordingly, the number of calls and information sources decreased.

Prior Federal Funding and Planning Built Capacity and Interagency Relationships, Which Facilitated the Federal Response

Federal funding and planning for pandemic preparedness prior to the onset of the H1N1 pandemic paid off by building capacity in several areas, including (1) vaccine production, (2) influenza diagnosis, and (3) antiviral drug development and stockpiling. First, the retrofitted influenza vaccine manufacturing facilities that HHS funded doubled the production capacity for H1N1 vaccine at two vaccine manufacturers, according to HHS.⁴⁵ These

⁴³See GAO, *Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy*, GAO-07-781 (Washington, D.C.: Aug. 14, 2007).

⁴⁴At the onset of the H1N1 outbreak, the President’s nominee for Secretary of Health and Human Services had not yet been confirmed. She was confirmed on April 28, 2009.

⁴⁵Department of Health and Human Services, *Report to Congress: June 2010 Report, Pandemic Influenza Preparedness Spending* (Washington, D.C., June 2010).

two manufacturers told us that the expanded capacity enabled them to start production of the H1N1 vaccine while they finished their production of seasonal influenza vaccine. Second, one of the influenza diagnostic tests that HHS's pandemic planning efforts helped fund detected the first case of H1N1 influenza as part of a clinical trial at the Naval Health Research Laboratory in San Diego, California. Third, the antiviral drug Peramivir—which was developed using pandemic preparedness funds—was made available for the first time during the H1N1 pandemic, and CDC delivered about 2,100 5-day treatment courses to hospitals.⁴⁶ Also, according to CDC officials involved in the response, no national shortage of adult antiviral drugs occurred during the H1N1 pandemic, which may have been due in part to prior federal and state stockpiling efforts. There was, however, a shortage of pediatric antiviral drugs in the fall of 2009.

Through interagency planning efforts, federal officials built relationships that helped facilitate the federal response to the H1N1 pandemic. Officials from HHS's ASPR and CDC, DHS, and Education stated that these interagency meetings, working together on existing pandemic and nonpandemic programs, and exercises conducted prior to the H1N1 pandemic built relationships that were valuable for the H1N1 pandemic response. Specifically, HHS officials said that federal coordination during the H1N1 pandemic was much easier because of these formal networks and informal relationships built during pandemic planning activities and exercises. For example, in developing the national pandemic strategy and national pandemic implementation plan, the HSC convened regular interagency meetings to facilitate cooperation and coordination across the federal government to prepare for an influenza pandemic. The NSS continued to hold these interagency meetings during the H1N1 pandemic response. Also, Education and CDC officials told us that in addition to these formal meetings, they had existing working relationships with each other that had been built while developing and managing a range of programs. Finally, officials from HHS, DHS, and other agencies held joint

⁴⁶The antiviral drug Peramivir was made available under an emergency use authorization (EUA) during the H1N1 pandemic. Peramivir was the first investigational drug to be made available under an EUA. During the Peramivir EUA period, CDC reported that it received 1,371 requests for Peramivir and delivered a total of 2,129 5-day adult treatment courses from the SNS to 563 hospitals in the United States within 24 hours of receipt of request. A study found that Peramivir was associated with recovery in most patients hospitalized with severe pneumonia associated with H1N1 influenza. See J.E. Hernandez et al., "Clinical Experience in Adults and Children Treated with Intravenous Peramivir for 2009 Influenza A (H1N1) Under an Emergency IND Program in the United States," *Clinical Infectious Diseases*, vol. 52, no. 6 (2011), 695-706.

pandemic exercises to test various parts of the plan. As we have previously reported, DHS officials have said that exercises offer the best opportunity—short of actual emergencies—to determine if plans are understood and work.⁴⁷ DHS officials stated that as a result of pandemic planning and exercises, DHS and other federal agency officials knew whom to contact within federal agencies when H1N1 influenza emerged. NSS and HHS officials reported to us in April 2011 that many of the same departments and officials are meeting regularly as part of a new group to discuss emerging pandemic threats.

Planning efforts also allowed federal and state officials to build upon preexisting relationships that were useful during the pandemic response. These relationships had been built through daily interactions implementing grant programs, developing state and local pandemic plans, and working together in pandemic planning exercises. For example, CDC held a pandemic planning exercise with other federal officials and 11 state and local jurisdictions in October 2008. During this exercise, officials practiced responding to a pandemic influenza situation. A senior CDC official said that preexisting relationships with states and localities allowed them to be frank, informal, and comfortable with each other when responding to the H1N1 pandemic. Georgia health officials told us that they spoke to CDC project officers daily during the H1N1 response to provide real-time situational awareness because of their relationships formed prior to the pandemic. Washington health officials also said that existing relationships with CDC officials helped their response efforts. Specifically, CDC revised school closure guidance based in part on experiences with school closures in Seattle, Washington. This revised guidance recognized that because the disease severity of H1N1 influenza was similar to that of seasonal influenza and the virus had already spread within communities, the focus was on keeping sick children and staff at home rather than closing schools as a way to stop the spread of the virus.

⁴⁷GAO, *Disaster Response: Criteria for Developing and Validating Effective Response Plans*, GAO-10-969T (Washington, D.C.: Sept. 22, 2010).

Failure to Meet Public Expectations about Vaccine Availability Diminished Government Credibility, but Some Practices for H1N1 Vaccine Distribution Were Reported to Be Valuable

H1N1 Vaccine Was Not Widely Available When Expected nor When Demand Was Highest

By the time H1N1 vaccine was widely available, the peak of H1N1 influenza activity had passed and many individuals were no longer as interested in getting vaccinated.⁴⁸ (See fig. 3.) The national pandemic implementation plan established a goal of expanding influenza vaccine manufacturing surge capacity for the production of pandemic vaccines to allow for the entire domestic population to be able to receive a vaccine within 6 months of a pandemic declaration.⁴⁹ During the H1N1 pandemic, the H1N1 vaccine was first available in the United States in October 2009, or almost 4 months after WHO's pandemic declaration, but was not widely available for all who wanted to be vaccinated until late December 2009. (See fig. 4 for a timeline of key events related to H1N1 vaccine production and distribution.) A RAND Corporation study found that at the onset of influenza activity, about half of adults were willing to get vaccinated,⁵⁰ but after the vaccine became available, CDC reported that only about 23 percent of adults actually were vaccinated.⁵¹

⁴⁸The geographic distribution of H1N1 influenza activity was most widespread during the weeks ending October 24, 2009, and October 31, 2009, when 48 of 50 states reported widespread influenza activity. Centers for Disease Control and Prevention, "Update: Influenza Activity – United States, 2009-10 Season," *Morbidity and Mortality Weekly Report*, vol. 59, no. 29, (2010).

⁴⁹See Homeland Security Council, *National Strategy for Pandemic Influenza Implementation Plan*, (Washington, D.C., May 2006).

⁵⁰J. Maurer, K.M. Harris, et al., "Does Receipt of Seasonal Influenza Vaccine Predict Intention to Receive Novel H1N1 Vaccine: Evidence from a Nationally Representative Survey of U.S. Adults," *Vaccine*, vol. 27 (2009), 5732-5734.

⁵¹Centers for Disease Control and Prevention, "Final Estimates for 2009-10 Seasonal Influenza and Influenza A 2009 (H1N1) Monovalent Vaccination Coverage – United States, August 2009 through May 2010," http://www.cdc.gov/flu/professionals/vaccination/coverage_0910estimates.htm (accessed Oct. 8, 2010).

Figure 3: H1N1 Influenza Activity and Vaccine Availability, October 2009 through January 2010

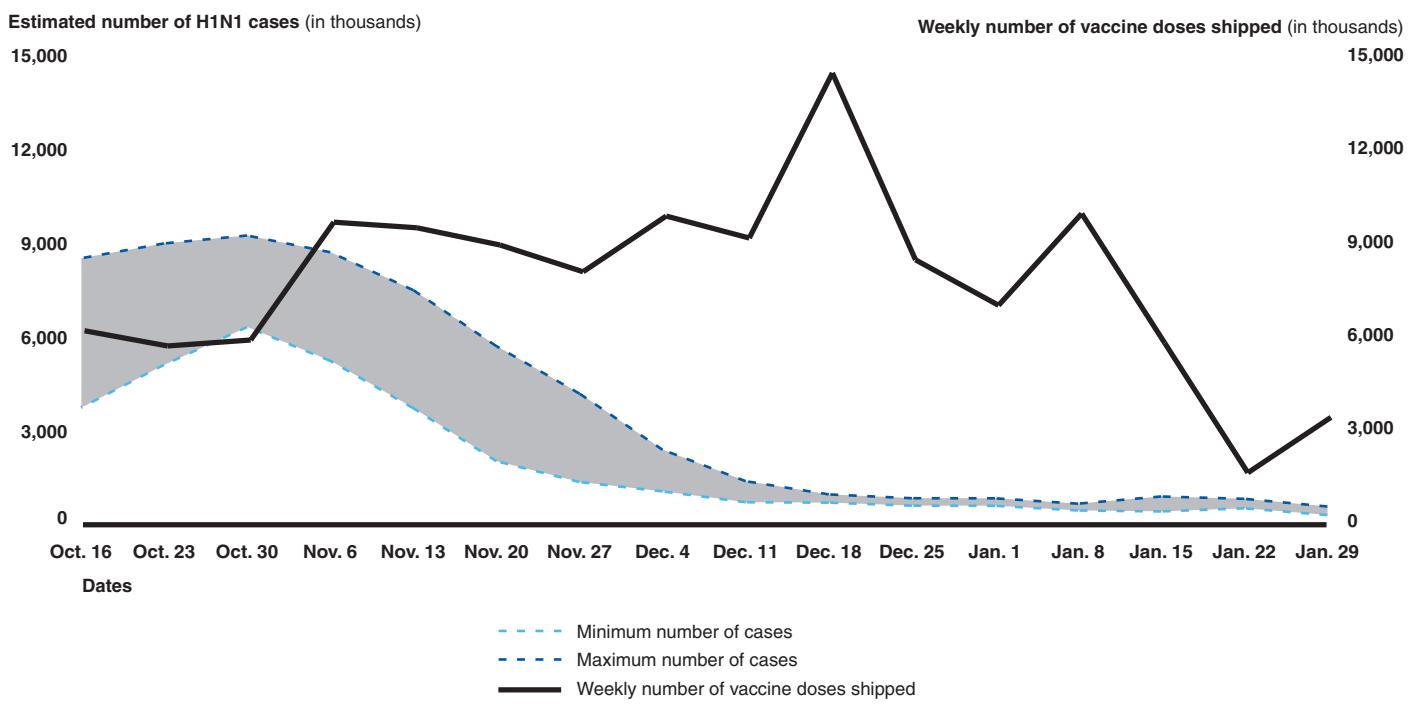


Figure 4: Key Events Related to 2009 H1N1 Vaccine Production and Distribution in the United States, April 2009 through November 2009



Sources: GAO analysis; James Gathany (photos).

The credibility of all levels of government was diminished when the amount of vaccine available to the public in October 2009 did not meet expectations set by federal officials. During the summer of 2009, HHS conveyed to state and local jurisdictions, and to the public, that a robust H1N1 vaccine supply, about 120 million to 160 million doses, was expected to be available in October 2009. Ultimately, only about 23 million doses of H1N1 vaccine were allocated for ordering by states and local jurisdictions at the end of October 2009, and because of the time required to order and ship the vaccine, fewer than 17 million doses were shipped out that

month.⁵² Consequently, the public had an unfavorable view of the federal government's ability to provide the country with the H1N1 vaccine. A Gallup survey of U.S. adults from early November 2009, found that 54 percent of adults said the federal government was doing a poor (41 percent) or very poor (13 percent) job of providing the country with adequate supplies of the vaccine.⁵³ An ASTHO report echoed that loss of government credibility also was a concern at the state level. ASTHO concluded that state health department officials felt that dealing with slow and variable vaccine delivery and shifting messages about vaccine availability overshadowed all of their other response activities.⁵⁴ For example, when vaccine availability was less than anticipated, state and local health departments had to cancel planned and publicized mass vaccination clinics and change their messages to the public about vaccination at a time when H1N1 influenza activity was peaking. Also, at the local level, health department officials in Fulton County, Georgia, stated that they canceled several school-based vaccination clinics because they lacked the H1N1 vaccine. According to these officials, once the H1N1 vaccine became available, parents were not interested in vaccinating their children because H1N1 influenza activity had already peaked in the area.

HHS has acknowledged that the H1N1 vaccine arrived too late in the response and noted the department is actively looking for ways to shorten the time required for vaccine production. The agency plans to use a portion of the remaining 2009 pandemic supplemental funds for these efforts. According to the Director of BARDA—who during the H1N1 pandemic response was responsible for overseeing the largest development and production of vaccine in U.S. history—once HHS staff were positioned at the vaccine manufacturing plants and manufacturers were required to report their time frames in a standard manner, HHS had a better understanding of the vaccine manufacturing process and the estimates for vaccine availability became more accurate in November 2009. A senior CDC official acknowledged that the uncertainty in the initial

⁵² As of December 2010, HHS allocated 138 million doses to states and local jurisdictions, provided 2.7 million doses to the Department of Defense, and donated 16 million doses internationally. About 127 million doses were distributed to states and local jurisdictions, 11 million less than the amount allocated. Not all distributed vaccines were administered.

⁵³ Gallup, *In U.S., 20% of Parents Unable to Get H1N1 Vaccine for Child* (Nov. 10, 2009), <http://www.gallup.com/poll/124220/Parents-Unable-H1N1-Vaccine-Child.aspx> (accessed Apr. 26, 2011).

⁵⁴ ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 20.

State and Local Jurisdictions Valued Flexibility in Implementing Vaccination Campaigns, but Differences across Neighboring Jurisdictions Led to Public Confusion

vaccine estimates was not adequately conveyed to state and local jurisdictions in the early days of the response effort.

Officials from state and local jurisdictions valued the flexibility that they had to implement their vaccine distribution plans. Although the federal government purchased the H1N1 vaccine and ACIP recommended that states and local jurisdictions initially provide it to individuals in the target groups, CDC allowed for state and local flexibility over vaccine distribution plans. NACCHO, as well as participants in a series of IOM workshops, reported that officials from state and local jurisdictions welcomed the flexibility to determine their own vaccine distribution plans. At the same time, state officials acknowledged that the flexibility, while appreciated, also led to confusion or the appearance of inequity, especially when the public became aware of different approaches taken in neighboring jurisdictions.⁵⁵ Participants in an IOM workshop reported that officials from jurisdictions that had approaches different from neighboring jurisdictions found it hard to communicate to the public about why one county or state was vaccinating a certain subset of their population while another was not.⁵⁶ For example, Snohomish County, Washington, initially included teachers in its target groups and conducted mass vaccination clinics, while neighboring Seattle-King County did not include teachers and distributed its initial supply of vaccine to physicians who were to vaccinate their patients. An official from the Seattle-King County health department reported that the public was confused by the differences. Washington health officials told us that they attempted to coordinate use of the target groups at the state level, but because local jurisdictions ultimately have control of local public health policies in the state, there were still differences between counties in implementation. Also, Vermont officials told us that the neighboring state of New York began vaccinating the general public beyond the target groups while Vermont was still waiting for guidance from CDC to widen its distribution.

CDC attempted to minimize confusion and anxiety by alerting the public that there would be differences in distribution methods. CDC's spokespeople emphasized this variation in the majority of the 18 press briefings that the agency held from September 2009 through December 2009 that we reviewed. A senior CDC official acknowledged the confusion

⁵⁵ NACCHO, *H1N1 Policy Workshop Report*, 11.

⁵⁶ Institute of Medicine, *The 2009 Influenza Vaccination Campaign: A Summary of a Workshop Series* (Washington, D.C.: The National Academies Press, October 2010), 31.

Use of a Central Vaccine Distributor Was Generally Cited as an Effective Practice, but Limitations in Sizes of Vaccine Orders Was Cited as Problematic

resulting from allowing state and local flexibility, but noted that the agency would make the same decision again because of the importance of local public health decision making.

CDC used a central vaccine distributor—building off the existing Vaccines for Children program—and this practice was generally cited as effective by association and state officials.⁵⁷ The Vaccines for Children program’s central distributor shipped the H1N1 vaccine from regional distribution centers that received the H1N1 vaccines from five vaccine manufacturers to individual providers or organizations identified by state and local jurisdictions. State and local health officials, in conjunction with professional associations such as the American Medical Association, identified providers who signed agreements to administer the H1N1 vaccine, including providers who had not previously participated in the Vaccines for Children program, such as obstetricians, gynecologists, and other physicians who treat and immunize adults. According to CDC officials, once H1N1 vaccine arrived at the central distributor’s regional distribution centers, 95 percent of the ordered doses of H1N1 vaccine were shipped out in accordance with CDC’s contract.⁵⁸ An official with the Association of Immunization Managers, which represents immunization program managers in state and local jurisdictions, involved in the response reported that use of the central distributor was a “best” practice during the H1N1 pandemic response because the central distributor was already in place and in operation. This official noted that she did not hear any issues or complaints from her association’s members about the use of the central distributor. Officials from four of the states we contacted also noted that the central distributor worked well. Alternatively, CDC could have shipped the H1N1 vaccine out to SNS receiving sites in states; CDC’s prior pandemic planning had focused on direct distribution by manufacturers to a limited number of state health department–designated sites. However, officials had decided that using a private distributor—that routinely distributes seasonal influenza and other vaccines—was a preferable method. CDC officials stated that because of the success of the central distributor during the H1N1 pandemic, CDC now views this method as the most efficient and effective method of vaccine distribution. State officials

⁵⁷Vaccines for Children is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of their families’ inability to pay. The program, administered by CDC, distributes pediatric vaccines to states and health care providers.

⁵⁸According to CDC officials, CDC’s contract with the distributor specified that all doses of H1N1 vaccine needed to be shipped out on the day the order was placed.

in two states reported that using the SNS sites instead of the central distributor would have caused logistical challenges.

While the use of a central vaccine distributor was generally cited as an effective practice by state and local health officials during the H1N1 pandemic, some state health officials noted challenges with the distribution process. Specifically, some state officials said that the central distributor's 100-dose minimum shipment requirement caused problems. As part of its contract with CDC, the central distributor required that shipments to each site include a minimum of 100 doses of H1N1 vaccine. Officials in three of the five states we contacted, as well as the U.S. Virgin Islands, told us that the 100-dose minimum ordering requirement caused difficulties because they had to break down the 100-dose shipments into smaller shipments so they could be shipped to smaller vaccine providers. Texas officials told us that the state hired a third-party contractor to receive and repackaging the shipments for smaller vaccine providers. ASTHO also cited this issue as a challenge, noting that the dosage order requirements caused delays in some providers receiving the H1N1 vaccine.⁵⁹ According to CDC officials, at the time that they were negotiating the distribution contract, the possibility existed that up to 600 million doses of H1N1 vaccine would need to be distributed as quickly and efficiently as possible, a magnitude that was unprecedented and untested.⁶⁰ At that time, CDC and the distributor determined that it would be inefficient and even cost prohibitive for the contractor to hire the additional staff to break packages into smaller units for distribution.

⁵⁹ ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 17.

⁶⁰ Because initial information suggested that two doses of H1N1 vaccine might be required, initial estimates for the number of H1N1 doses that would need to be shipped included the possibility of up to 600 million doses.

Public Surveys Generally Found CDC's Public Communication Campaign to Be Effective, but Communication Materials Were Not Accessible for All Populations

Public Surveys Found CDC's Communication Campaign to Be Effective

Public surveys, state officials, and representatives from professional associations generally found CDC's public communication campaign to be effective. To gauge the effectiveness of its communication campaign and other aspects of the H1N1 response, CDC and others contracted with the Harvard School of Public Health to conduct regular surveys of the public regarding the H1N1 response. One study, conducted as part of this initiative in March 2010 and April 2010 with a nationally representative sample of U.S. adults aged 18 years and older, found that 70 percent of adults rated CDC's H1N1 influenza communication campaign as excellent (25 percent) or good (45 percent).⁶¹ Ratings of the communication campaign did not differ considerably among different ethnic groups. Further, more than half of adults reported seeing or hearing the key H1N1 protection and prevention messages, which included messages suggesting that people should get the H1N1 vaccine, wash their hands or use hand sanitizer frequently, stay home from work or school if sick, and cough or sneeze into one's elbow or shoulder. A professional association official as well as state health officials from three of the states we contacted also credited these personal infection control messages when we asked them about CDC's communication with the public. The same survey found that 89 percent of adults said they would trust CDC a great deal (59 percent) or somewhat (30 percent) for information about protecting themselves or their families from H1N1 influenza.

According to CDC officials, the agency's communication with the public was based on the agency's decision to be transparent and open with the public about both known and unknown information. CDC's crisis communication principles—which it formally articulated in its H1N1

⁶¹R. Blendon, G. SteelFisher, M. Bekheit, and M. Herrmann, "The Public's Response to H1N1: A Multiethnic Perspective," Harvard Opinion Research Program, Harvard School of Public Health, <http://www.hsph.harvard.edu/research/horp/project-on-the-public-response-to-h1n1/> (accessed Jan. 6, 2011).

communication plan—emphasize transparency and acknowledgment of uncertainty, as well as a commitment to frequent updates as new information emerges.⁶² Specifically, CDC established four goals during the pandemic to guide communication efforts:

- Provide timely, accurate, and credible information about the public health threat and government actions to prevent 2009 H1N1 influenza and mitigate its impact.
- Increase public awareness, knowledge, and adoption of influenza prevention, mitigation, and treatment recommendations. These recommendations included promotion of vaccines, community measures, personal and institutional infection control, and the correct use of antiviral drugs.
- Guide public expectations for change and variability related to prevention and mitigation recommendations.
- Protect the health of the public while minimizing social, economic, and educational disruption.

CDC held frequent press briefings to provide timely dissemination of new information on the evolving situation. For example, during the early days of the H1N1 outbreak, CDC held almost daily press briefings. Officials from all five states we contacted and the National Governors Association noted that the agency's spokespersons throughout the H1N1 pandemic were generally effective. The Director of the Center for Infectious Disease Research and Policy at the University of Minnesota noted that CDC's communication campaign gave the public the sense that the federal government was in charge of the pandemic response. CDC also held a 2-day conference in August 2009 to educate the media about influenza and what the fall influenza season could entail. CDC officials said the conference provided context for the media representatives in attendance, fostered an environment of transparency, and established a relationship between media and CDC officials. In addition to the interactions with the media, CDC used a variety of tools to reach the public directly (see fig. 5). According to CDC officials, communications was an integrated part of the response, with senior communications officials from across the agency represented when all major decisions were made. These officials noted

⁶²CDC developed an internal H1N1 communications plan to guide its communications efforts during the response.

that the inclusion of these representatives when decisions were being made allowed for a two-way conversation where policy experts took into consideration the perceptions and concerns of the public.

Figure 5: CDC Communication Tools Used during the H1N1 Pandemic Response

CDC officials reported using a number of different tools to reach the public with their messages:

- CDC used traditional media outlets, such as newspapers, television, and radio.
- CDC used the flu.gov Web site to provide a single source of information about the H1N1 pandemic.
- CDC introduced content syndication, which allowed CDC to automatically update entities that subscribed to CDC and CDC's Web sites when CDC updated its own information.
- CDC used social media, such as Twitter and blogs, to share information.

Source: GAO analysis.

In addition, state and local jurisdictions appreciated CDC's efforts to keep them informed of ongoing changes. For example, CDC had representatives from professional associations representing state and local health officials at its Emergency Operations Center during the second wave of the pandemic, which occurred in fall 2009.⁶³ This was the first time that this type of involvement had happened, according to the association and CDC officials. According to CDC officials, the inclusion of these organizations helped foster transparency and allowed for the federal government to better understand the perspectives of state and local jurisdictions. Officials from Texas's health department noted that CDC shared talking points with them before conference calls. These officials told us that this gave them credibility because they were aware of information before it was shared broadly. In addition, Georgia health officials told us that they appreciated the frequent information sharing from sources such as CDC phone calls with states and the Web site flu.gov, which disseminated information during the H1N1 pandemic.

⁶³CDC's Emergency Operations Center is the agency's command center for monitoring and coordinating CDC's emergency response to public health threats in the United States and abroad.

State and Local Jurisdictions Cited Need for More Timely Communication Materials for Non-English-Speaking Populations

State and local jurisdiction officials we spoke with wanted CDC to provide more communication materials for non-English-speaking populations. Specifically, three of the states we contacted—as well as the National Indian Health Board—reported that in order to serve their populations, they needed CDC communication materials, including posters and public service announcements, translated into additional languages in a more timely manner. Some state officials and ASTHO also expressed that it would be more efficient for CDC to translate materials once than for each state or local jurisdiction to spend the resources to do so individually or to rely on nonexperts for translation. Officials in Seattle-King County, Washington, reported that they had to translate materials into 20 languages to meet their jurisdiction’s needs. Similarly, in Vermont, health officials reported that they needed to translate and print materials into 7 languages, only 2 of which were included in CDC’s translated materials. The Vermont health officials told us that the process of translation took several weeks, which they said affected the vaccination rates among these populations. Following the H1N1 pandemic, an ASTHO report recommended that the federal government routinely take the lead in translating pandemic materials into multiple languages.⁶⁴

CDC officials explained the range of translation services they offered, but also noted that they could take additional measures to assist states with translation. CDC communications officials said that the agency translated its television and radio public service announcements about the H1N1 pandemic into Spanish and translated written materials into a range of languages.⁶⁵ CDC officials explained that they select the range of translation services they will offer from a list of over 100 languages and explained that these selections are based on the geography of the situation, input from state and local public information officers, input from stakeholders, and information from the searches that users complete on the CDC Web site. CDC officials also told us that because information about the pandemic was changing so quickly, it was challenging for CDC to translate all of the information in a timely manner. A CDC official noted that the agency could serve some additional roles in facilitating translation

⁶⁴ ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 28.

⁶⁵ According to CDC officials, CDC’s guidance is typically translated into 5 languages—Spanish, Vietnamese, Chinese, French, and Tagalog—but that during the H1N1 pandemic, documents were also translated regularly into the following 12 languages determined in consultation with HHS’s Office of Minority Health: Arabic, Russian, Japanese, Korean, German, Burmese, Italian, Somali, Khmer, Kirundi, Amharic, and Oromo.

for states, such as working with state partners to establish a clearinghouse for already-translated materials as well as a plan to identify and address translation gaps that avoids duplication of effort and helps ensure consistency and accuracy. For translation into additional languages, CDC officials noted that states could use the PHER grant funds.

Deployment of the SNS Met the Established Goal, but Gaps in Planning Were Identified

SNS Deployment Met Goal, but State and Local Jurisdictions Cited Need for Improved Communication from CDC on the Timing and Content of Shipments

While deployment of supplies from the SNS met the established goal, officials from state and local jurisdictions reported a need for improved communication about the timing and contents of shipments. Five days after the initial diagnosis of H1N1 influenza, on April 26, 2009, CDC released a quarter of the antiviral drugs and other supplies—including 11 million courses of antiviral drugs and 39 million face masks and respirators, gowns, and gloves. Seven days later, on May 3, 2009, all states and local jurisdictions—except two of the Pacific Island territories—had received their SNS allocations.⁶⁶ Officials we interviewed in three states and participants in a series of IOM workshops noted that officials from state and local jurisdictions did not always know when SNS shipments would be arriving or what would be included in the shipments.⁶⁷ For example, Nebraska officials reported that they were told a shipment would be arriving at 6:30 a.m., but the materials arrived earlier—at 2:30 a.m. Nebraska officials were able to meet the delivery trucks with a team of staff, but the shipment contained only two cases of gloves, which was not what they anticipated. Officials from Texas reported that SNS delivery schedules were often not adhered to and the lists of what would be in the shipments were incorrect. Georgia officials reported that they were not informed before the SNS supplies arrived at state warehouses, which meant that they were not able to provide the planned security for the supplies.

⁶⁶ According to CDC's SNS officials, this time frame met CDC's established goal for timely release of the SNS supplies.

⁶⁷ Institute of Medicine, *Medical Countermeasures Dispensing: Emergency Use Authorizations and the Postal Model: Workshop Summary* (Washington, D.C.: The National Academies Press, October 2010), 16.

CDC officials told us that they took a variety of steps during the second wave of the pandemic to improve collaboration with the states about the timing and contents of the SNS shipments. Specifically, they noted that they recognized that states were not operating on 24-hour schedules, as had been assumed in prior SNS planning efforts. Accordingly, CDC's SNS officials explained that they changed their delivery schedules to only deliver supplies during working hours. They also told us that when they contacted the states to coordinate the timing of SNS shipments, they also provided more information on the contents of the shipments. These officials also told us that they revised the SNS procedures to institutionalize these measures.

Not All Models of Respirators in the SNS Were Commonly Used, and Guidelines Were Conflicting

According to some state and local officials, one gap in SNS planning was that the respirators provided through the SNS were different from those used by state and local jurisdictions. IOM reported in its summary of a series of workshops that the respirator models—also called N95 respirators—that state and local jurisdictions (and subsequently hospitals and other health care facilities) received from the SNS were not the same as the models hospitals regularly used, nor was a standard model provided, which necessitated additional fit testing by recipients.⁶⁸ To be optimally effective, respirators require a tight facial seal, thus individual “fit testing” is required. In Washington, state officials and Snohomish County officials told us that they received an unfamiliar brand of respirators in their SNS shipment that required fit testing of equipment that they did not have available. ASTHO also reported that state and local officials found the SNS respirators problematic and reported that states did not know which models of respirators were in the SNS or which models would be delivered.⁶⁹ CDC officials responsible for the SNS acknowledged problems with familiarity with the models of respirators in the SNS and reported that they are looking into a range of solutions, including standardizing the type of respirators included in the SNS and

⁶⁸IOM, *Medical Countermeasures Dispensing: Emergency Use Authorizations and the Postal Model: Workshop Summary*, 14.

⁶⁹ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 23.

providing a catalog of stored supplies to states.⁷⁰ An official from CDC's National Institute for Occupational Safety and Health told us that the institute is also researching the next generation of respirators for health care workers. Another CDC division is also working with partners to develop reusable masks specifically designed for health care settings.

State and local government officials were also confused by conflicting federal and nonfederal guidance on the need for health care workers to wear respirators. In 2007, HHS and the Department of Labor issued joint guidance recommending that health care workers use respirators when in close contact with patients who have confirmed or suspected influenza during a pandemic. In May 2009, CDC released infection control guidance for clinicians to use during the H1N1 outbreak that was consistent with the 2007 guidance. Further, a September 2009 study by IOM, which was requested by CDC and Department of Labor's OSHA, agreed with the existing 2007 guidance in the specific case of H1N1 influenza.⁷¹ However, conflicting guidance by other groups caused confusion during the H1N1 pandemic. The Infectious Disease Society of America and WHO recommended that health care workers only be required to wear respirators during health care procedures that involve specific types of exposure, such as intubation,⁷² resuscitation, or open suctioning of the respiratory tract. According to HHS officials, many clinicians preferred to adhere to the infection control procedures that they use for seasonal influenza. An ASTHO report noted that conflicts in guidance left health care and other affected organizations wondering which guidance to follow. Further, ASTHO reported that the requirement for health care workers to wear respirators resulted in supply shortages and required extra time and resources by health care facilities for fit testing.⁷³ Officials

⁷⁰CDC officials explained that the SNS respiratory devices they had purchased for the SNS were based on perceived urgency to rapidly acquire and store the first available N95 respirators and surgical masks using earlier pandemic preparedness funds. They acquired N95 respirators and surgical masks based on product availability and were not able to plan to procure specific models to match local hospital needs. During the H1N1 pandemic, the SNS shipped these N95 respirators and surgical masks to augment state and local capabilities.

⁷¹See Institute of Medicine, *Respiratory Protection for Healthcare Workers in the Workplace Against Novel H1N1 Influenza A: A Letter Report* (Washington, D.C.: The National Academies Press, Sept. 1, 2009), 4.

⁷²Generally, intubation is the introduction of a tube into an individual's airway to facilitate breathing.

⁷³ASTHO, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Influenza Pandemic*, 23.

from OSHA told us, and IOM reported, that the available guidance is contradictory because scientific research about routes of disease transmission and respirator efficacy is inconclusive. Additionally, OSHA officials acknowledged that there is currently an inadequate supply of respirators to meet demand if all health care workers followed the existing guidance.

SNS Planning Did Not Account for the Need for Long-Term Storage or Recovery of Unused SNS Materials

Another gap identified in SNS planning was related to long-term storage of unused SNS materials. During the response to the H1N1 pandemic, some of the state officials that we interviewed told us that they did not use all of their SNS supplies. Nebraska officials, for example, told us that they only used a few cases of SNS materials that they received and were storing the remaining SNS materials in a state facility. Vermont officials reported that they did not use all of their SNS supplies and, as a result, were paying for storage as of June 2010. These state officials told us that they did not know what to do with the remaining SNS items. A CDC official who works on SNS issues acknowledged that the federal government did not have plans for the handling of states' unused SNS materials. He said that long-term inventory management or return of SNS items to the federal government was not a part of SNS exercises because distribution plans were based on a more severe pandemic scenario or other emergencies where all available supplies would be used quickly after distribution. The CDC official said that the agency needs to plan for alternative scenarios when the commercial market may be able to handle the demand for items in the SNS.

In June 2010, HHS's FDA provided guidance to CDC on the disposal of materials in anticipation of the end of emergency use authorizations, which allowed potentially helpful countermeasures to be used for unapproved uses to protect the public health. For example, FDA advised that states could hold on to respirators for a possible future public health emergency or distribute the respirators to be used in a manner consistent with their clearances. In its guidance, FDA also advised that state officials could continue to hold onto FDA-specified antiviral drugs for use in a future emergency situation, provided that they are stored appropriately.

Federal Agencies Are Completing After-Action Reports; Next Steps, Including Sharing with Key Stakeholders, Are Unclear

Federal Agencies Were Asked to Complete H1N1 Pandemic After-Action Reports by the NSS

According to the NSS, all federal agencies were asked to complete after-action reports appropriate to their level of involvement in the H1N1 pandemic response. The NSS relayed to us in November 2010 that while it did not establish guidelines for these after-action reports, it was monitoring the status of the reports. HHS officials told us that NSS last requested that HHS report on the status of its H1N1 after-action reports and follow-up activities in September 2010.

The NSS stated in April 2011 that it had not determined whether it would synthesize the federal agency after-action reports into a single governmentwide after-action report or if it will make the after-action reports available to key stakeholders, such as state and local governments. Nevertheless, a DHS official commented that sharing lessons from the reports with stakeholders would foster a spirit of government transparency and might help build stakeholder trust.

Officials from HHS, DHS, and Education confirmed that they are completing their H1N1 pandemic after-action reports. The departments took different approaches to collecting information for these reports, and as of spring 2011, it was unclear whether the final reports will be made publicly available or shared with key stakeholders.

- HHS's process for completing its after-action report involved soliciting information from other federal and state agencies, as well as other response partners, such as health care providers. The process included a survey of experts across the federal government who had knowledge of HHS's H1N1 pandemic response; in-depth interviews with experts to assess the agency's H1N1 pandemic response; and stakeholder engagement sessions, conducted via webinars, with entities such as states, localities, private sector partners, and national trade associations. According to HHS officials, as of April 2011, the HHS after-action report was being reviewed within the department. HHS

officials also reported that the dissemination plans for the report were not finalized. HHS officials did report that the agency incorporated lessons learned from the H1N1 pandemic into its update of the National Vaccine Plan, which describes initiatives to enhance education on the safety of vaccines and vaccination practices and to assist providers and the public in making informed decisions regarding vaccination.⁷⁴ In addition to the department's activities to prepare an after-action report, individual agencies have also taken steps to incorporate lessons learned into their planning activities. For example, in March 2011, CDC held an exercise to incorporate lessons learned from the H1N1 pandemic into planning for a possible future pandemic. During this exercise, CDC officials worked with representatives from other parts of HHS, associations, as well as states and local jurisdictions to simulate a response to an avian influenza pandemic, which would likely have a higher fatality rate than the H1N1 pandemic. FDA also revised its Emergency Operations Plan to reflect lessons from the agency's response to the pandemic. In addition, HHS officials told us that they plan to hold exercises with DHS to test shared leadership roles.

- DHS's after-action report process was led by the department's Office of Health Affairs. The Office of Health Affairs collected its information through a series of planning conferences, after-action discussions, and online surveys of agency officials.⁷⁵ The after-action report includes both strengths and areas for improvement to enhance future departmental performance during a pandemic or other all-hazards incident and is accompanied by a formal improvement plan. The DHS after action report was signed by the Secretary of Homeland Security on May 20, 2011, and DHS officials told us that they have shared the report with the NSS. DHS officials also told us that they are in the process of developing their dissemination plans for the report's findings, including plans for sharing the findings with state and local governments.
- Education's after-action report will be based on information gathered during a working group meeting in February 2010 that included discussions of how Education responded to the H1N1 pandemic, what

⁷⁴The *National Vaccine Plan* focuses on all vaccines, not solely influenza vaccines.

⁷⁵In May 2009, the Secretary of Homeland Security submitted a memorandum to the White House with lessons learned from the first wave of the H1N1 pandemic and next steps to undertake in preparation for the expected second wave in the fall of 2009.

lessons were learned, and what the agency would do differently during another pandemic. As of March 2011, Education's after-action report had not been finalized, and Education did not have dissemination plans.

- OSHA officials also told us that they have completed an H1N1 after-action report.

NSS Reported Plans for a Broad Approach to Preparedness

In April 2011, a senior NSS official reported that the NSS had no plans to update the national pandemic implementation plan to incorporate lessons learned from the H1N1 pandemic response; however, these lessons may be incorporated into departments' individual operational plans. Instead of updating the national pandemic implementation plan, NSS officials reported that they are coordinating a larger effort to transition national preparedness from a dependence on fixed plans for specific threats to an approach based on the capabilities needed for a variety of hazards, or an all-hazards approach.⁷⁶ Furthermore, the NSS did not indicate how the after-action reports—and the associated lessons learned—will be used in future planning and preparedness efforts. Specifically, as discussed above, the NSS has not yet determined if it will share the lessons from the after-action reports with key stakeholders, such as state and local governments. As we have previously reported, stakeholder involvement during the planning process is important to ensure that both the federal government's and key stakeholders' responsibilities and resource requirements are clearly understood and agreed upon.⁷⁷ We have previously recommended that the HSC, which is supported by the NSS, update the national pandemic implementation plan to incorporate information from exercises and other experiences, such as the H1N1 pandemic.⁷⁸ Indeed, the *National Response Framework*—which outlines the manner in which the federal government responds to domestic incidents—specifies that evaluation and continual process improvement are cornerstones of effective

⁷⁶The White House released Presidential Policy Directive 8 on March 30, 2011. This directive aims to facilitate an integrated, all-of-nation, capabilities-based approach to preparedness.

⁷⁷[GAO-07-781](#).

⁷⁸[GAO-07-781](#) and [GAO-10-73](#).

preparedness.⁷⁹ It notes that improvement planning should develop specific recommendations for changes in practice, timelines for implementation, and assignments for completion.⁸⁰ In addition, DHS has defined the national preparedness system as a continuous cycle that involves four main elements: (1) policy and doctrine, (2) planning and resource allocation, (3) training and exercises, and (4) an assessment of capabilities and reporting.⁸¹

Conclusions

The H1N1 pandemic was the first human influenza pandemic in more than four decades. As such, it provided the first real-life opportunity to test and implement key aspects of the federal government's plans to respond to a pandemic, including those in the 2005 national pandemic strategy and the 2006 national pandemic implementation plan. Thus, it is important to capture the lessons from the experiences of this event, both in terms of response actions that worked as well as those that could be improved.

It is also imperative to learn from these lessons by incorporating them into future planning and exercising efforts so that the nation can be better prepared when the next influenza pandemic occurs. These lessons may also be more broadly applicable to other hazards or emergencies that require response measures, such as activation of the SNS. They are also relevant to key stakeholders, such as state governments, which were instrumental in this response and would play a key role in a future response. All sectors of society, including governments, nonprofit organizations, and the private sector, will need to be involved in preparedness for a future pandemic. Accordingly, key stakeholders will need to adjust their own plans and understand their critical roles in order to be prepared to work effectively under difficult and challenging circumstances.

⁷⁹Issued by DHS in January 2008, the *National Response Framework* is the doctrine that guides how federal, state, local, and tribal governments, along with nongovernmental and private sector entities, will collectively respond to and recover from all hazards, including catastrophic disasters such as Hurricane Katrina.

⁸⁰DHS, *National Response Framework*, 32.

⁸¹Department of Homeland Security, *National Preparedness Guidelines* (Washington, D.C., September 2007).

These lessons also have some important limitations. Specifically, while the H1N1 pandemic provided the opportunity to test and implement many aspects of the federal government's plans to respond to a pandemic, not all parts of these plans—such as those dealing with critical infrastructure protection and implementing border and trade measures—were tested. In addition, the shared leadership structure was not fully tested, and states raised concerns about their brief experience with these shared leadership roles. HHS's and DHS's plans to test this structure will be an important step to addressing this gap. These aspects may prove to be necessary in response to a future pandemic, given that avian and other strains of influenza remain a threat.

Our review of the federal government's response to the H1N1 pandemic highlighted several key lessons:

- Planning and preparedness pay off. While the actual H1N1 outbreak and pandemic differed from the avian influenza pandemic scenario that was the basis for the planning, many of the funding and planning activities—including funding for vaccine production capacity, planning exercises, and interagency meetings prior to the H1N1 pandemic—positioned the government to respond effectively. The interagency working group, convened by the NSS, fostered relationships that proved advantageous during the response.
- Effective communication on the availability of vaccine is central to a successful response. Although the federal government was able to purchase and distribute millions of doses of H1N1 vaccine, the vaccine was not widely available when the public expected it and at the peak of demand. Because the failure to effectively manage public expectations can undermine government credibility, it is essential that vaccine production efforts be paired with effective communication strategies regarding the availability of the vaccine.
- Timely, accessible information from CDC is valuable. The public proved to be highly receptive to the information CDC disseminated regarding the pandemic and what individuals could do to reduce their susceptibility to H1N1 influenza. However, the effectiveness of communication materials was diminished for some non-English-speaking populations when translated materials were not available to them in a timely manner. We heard from state and local health jurisdictions that they need materials in more languages, and they suggested that communications would be more accurate and translated more efficiently if key materials were translated centrally.

- Given the key role of the SNS in a public health emergency, consideration of logistics, inventory, and different scenarios is important in planning for SNS deployment. The largest deployment of the SNS to date occurred during the H1N1 pandemic response, but several issues emerged because scenarios arose that had not been anticipated. Resolving these issues now—in planning for future SNS deployment—will allow for better use of SNS resources during the next public health emergency.

Novel strains of influenza, including avian influenza strains, will continue to pose the threat of an influenza pandemic that could be more severe than the H1N1 pandemic. Accordingly, the failure to learn from the federal government's response to the H1N1 pandemic could be costly in terms of lives and resources, regardless of whether future planning is specific to a pandemic scenario or if it is incorporated into a broader “all-hazards” planning scenario. Although the NSS has requested that federal agencies prepare after-action reports, NSS officials have not decided how they will work with HHS and DHS to incorporate these lessons into any future planning, as called for by the *National Response Framework*, or how they will share these lessons with key stakeholders.

Recommendations for Executive Action

We recommend that the Homeland Security Council direct the National Security Staff to take the following two actions:

- In order to help the federal government prepare for a future influenza pandemic, work with the Departments of Health and Human Services and Homeland Security—as well as other federal agencies and state and local jurisdictions, as applicable—to update planning and exercising by incorporating lessons learned from federal agencies’ H1N1 after-action reports and the lessons we identified from the H1N1 pandemic. These lessons may include
 - developing communication strategies for better managing public expectations about pandemic vaccine availability while working to reduce the length of time required to produce a pandemic vaccine;
 - identifying state and local jurisdictions’ need for materials for non-English-speaking populations and examining ways to facilitate the timely and efficient translation of key communication materials; and
 - updating SNS plans by identifying tools for tracking SNS supplies, ensuring that the supplies in the SNS meet the needs of states and local jurisdictions, and accommodating previously unanticipated scenarios, such as the need for possible long-term storage or recovery of unused supplies.

- In order to help key stakeholders prepare for a future influenza pandemic or other public health emergencies, work with the Departments of Health and Human Services and Homeland Security—as well as other federal agencies, as applicable—to share the relevant findings of their after-action reports with key stakeholders, such as state and local governments.

Agency Comments and Our Evaluation

We provided a draft report for review and comment to the Associate General Counsel for the NSS, which works on behalf of the HSC, as well as the Secretaries of Health and Human Services, Homeland Security, Labor, and Education. The Secretary of Education did not provide any formal comments.

A legal advisor to the NSS did not provide written comments to be included in the final report, but agreed that the NSS would take the report and its recommendations under advisement.

In written comments, the HHS Assistant Secretary for Legislation responded that HHS generally agreed with our findings, and stated that its forthcoming after-action report will highlight several of the key themes that we address in our report. He also noted that HHS is already taking actions to address some of our findings, such as, reducing the time needed to make a pandemic influenza vaccine available and examining ways to make financial resources available during an emergency to states and local jurisdictions. He also provided technical comments, on behalf of HHS, which we incorporated as appropriate.

In written comments, the Director of the DHS GAO/Office of the Inspector General Liaison Office stated that DHS remains committed to working with the HSC, the NSS, HHS, and other relevant stakeholders to fulfill its shared leadership responsibility for pandemic influenza response. He also provided technical comments, on behalf of DHS, which we incorporated as appropriate.

On behalf of the Department of Labor, the Assistant Secretary for Occupational Safety and Health responded that OSHA provided an important contribution to the federal pandemic response by protecting workers' safety and health during the H1N1 pandemic. The Assistant Secretary further explained that OSHA has drafted an after-action report, which explains that the full range of OSHA's training, education,

enforcement, and public outreach programs were used to help employers and workers protect themselves at work during the H1N1 pandemic.

HHS, DHS, and OSHA's comments are reprinted in appendices III through V.

We are sending copies of this report to the HSC, the Secretary of Health and Human Services, the Secretary of Homeland Security, the Secretary of Education, the Secretary of Labor, and appropriate congressional committees. The report also is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Bernice Steinhardt at (202) 512-6543 or steinhardt@gao.gov or Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.



Bernice Steinhardt
Director, Strategic Issues



Marcia Crosse
Director, Health Care

Appendix I: Information on Selection Criteria for Five Selected States

To examine how states and local jurisdictions used the grant funds and interacted with federal departments during the response, we interviewed officials involved in the H1N1 pandemic response in a sample of five states: Georgia, Nebraska, Texas, Vermont, and Washington. We chose these states to provide insight into the experiences of a range of states; however, their experiences are not generalizable to all 50 states.

The sample of five states was selected to reflect a range of six characteristics:

- Interim vaccination rate for initial target groups
- Census region
- First week of reported widespread influenza activity
- Public Health Emergency Response (PHER) grant funding
- The 2008 population (in thousands)
- Public health structure

Table 3 lists data for each state on each characteristic.

Table 3: Data for Selected States

State	Interim vaccination rate for initial target groups (percentage) ^a	Census region	First week of reported widespread influenza activity ^b	PHER grant funding ^c	2008 Population (in thousands) ^d	Public health structure ^e
Georgia	22.7	South	5/09/2009	\$39,253,852	9,686	Hybrid
Nebraska	39.6	Midwest	7/11/2009	\$10,251,928	1,783	Hybrid
Texas	20.8	South	5/09/2009	\$93,258,556	24,327	Hybrid
Vermont	52.5	Northeast	10/17/2009	\$5,882,237	621	Centralized
Washington	37.5	West	9/19/2009	\$27,920,746	6,549	Decentralized

Source: GAO analysis of Department of Health and Human Services, Association of State and Territorial Health Officials, and U.S. Census Bureau data.

^aInterim vaccination rate for initial target groups is based on reported vaccination rates from October 2009 through January 2010. See Centers for Disease Control and Prevention, "Interim Results: Influenza A (H1N1) 2009 Monovalent Vaccination Coverage – United States, October through January 2010," *Morbidity and Mortality Weekly Report*, vol. 59, no. 12 (April 2010), 363.

^bThis is the first week that the state reported widespread influenza activity based on CDC's FluView from April 11, 2009, through December 26, 2009.

^cThis shows the total PHER grant funding for PHER phases one through three, as reported in CDC guidance to states.

^dThis is based on data reported by the U.S. Census Bureau in the *Statistical Abstract of the United States*, 2008.

⁶This is based on the Association of State and Territorial Health Officials' *Profile of State Public Health*, Volume 1. In a centralized structure, state health departments provide local public health services. In a decentralized structure, local health departments often collaborate with, but are organizationally independent of, state public health departments. In a hybrid structure, consumers may receive public health services from either the state or through agencies organized or operated by local governments, depending on the jurisdiction. In some cases, in hybrid structures state and local health departments share responsibility for providing services at the local level.

Appendix II: Full Text for Figures 1, 2, and 4 on Lessons from the H1N1 Pandemic

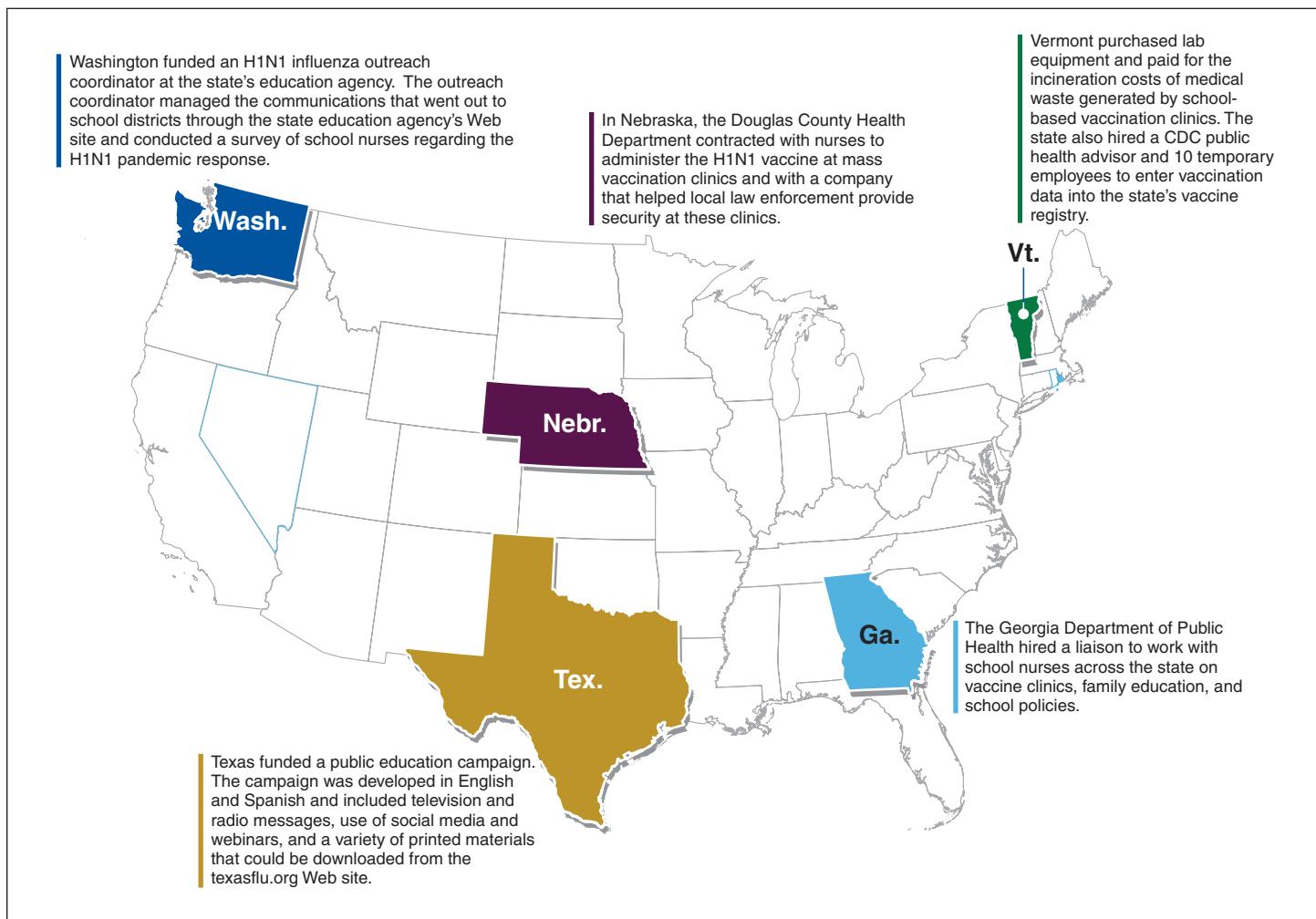
The following information appears as interactive content in the body of the report when viewed electronically.

Figure 6: Key Events Related to the H1N1 Pandemic in the United States, April 2009 through August 2010 (Printable Version)

Key Events Related to the H1N1 Pandemic in the United States, April 2009 through August 2010 (Printable Version)											
2009			2010								
April	May	June	July	August	September	October	November	December	January	February	March
April 15, 2009 The first U.S. case of H1N1 influenza is detected in California	April 23, 2009 CDC holds its first press briefing to address its response to the increasing number of U.S. H1N1 influenza cases	June 11, 2009 WHO declares the H1N1 outbreak a human influenza pandemic	May 5, 2009 CDC revises school closure guidance to recommend against school closures in cases with students with confirmed or suspected cases of H1N1 influenza	July 9, 2009 The White House, DHS, HHS, and Education hold an H1N1 Preparedness Summit for state and local governments during which the <i>National Framework for 2009-H1N1 Influenza Preparedness and Response</i> is discussed	July 10, 2009 The Secretary of Health and Human Services announces the availability of \$350 million in funding for states for the H1N1 pandemic response	October 5, 2009 The first H1N1 vaccine doses are administered	October 24, 2009 The President declares a national emergency based on the National Emergencies Act	November 10, 2009 FDA approves a fifth manufacturer to produce a H1N1 vaccine	December 24, 2009 U.S. public health emergency declaration ends	January 24, 2010 WHO declares an end to the H1N1 pandemic	February 10, 2010 WHO declares an end to the H1N1 pandemic
April 26, 2009 The Acting Secretary of Health and Human Services declares H1N1 influenza a U.S. public health emergency; CDC releases 25 percent of influenza supplies from the Strategic National Stockpile to states and local jurisdictions for the H1N1 influenza response	April 28, 2009 CDC issues interim guidance recommending that schools close for up to 7 days in cases of students with confirmed or suspected H1N1 influenza	April 29, 2009 The first U.S. H1N1 influenza death is reported in Texas	June 24, 2009 The President signs the Supplemental Appropriations Act, which provides HHS with as much as \$7.65 billion in supplemental funding to address the H1N1 pandemic	September 15, 2009 HHS's FDA approves four manufacturers to produce H1N1 vaccine	October 2009 The first H1N1 vaccine doses are administered	November 10, 2009 FDA approves a fifth manufacturer to produce a H1N1 vaccine	December 24, 2009 U.S. public health emergency declaration ends	January 24, 2010 WHO declares an end to the H1N1 pandemic	February 10, 2010 WHO declares an end to the H1N1 pandemic	March 10, 2010 WHO declares an end to the H1N1 pandemic	April 10, 2010 WHO declares an end to the H1N1 pandemic

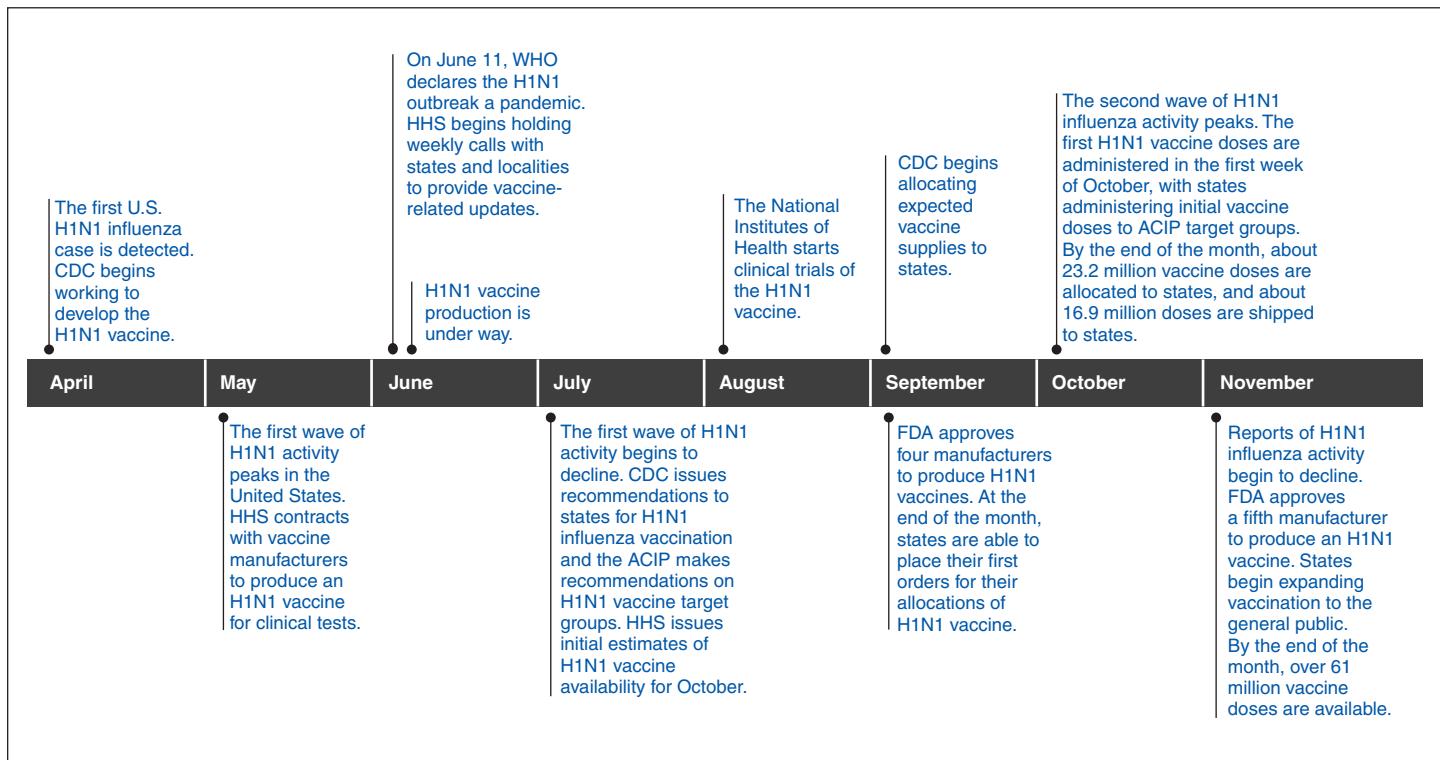
Source: GAO analysis.

Figure 7: Examples of Ways That State and Local Jurisdictions Used the PHER Grants (Printable Version)



Sources: GAO analysis of state data; Map Resources (map).

Figure 8: Key Events Related to 2009 H1N1 Vaccine Production and Distribution in the United States, April 2009 through November 2009 (Printable Version)



Source: GAO analysis.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

Bernice Steinhardt
Director, Strategic Issues
Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

JUN 01 2011

Dear Ms. Steinhardt and Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "INFLUENZA PANDEMIC: Lessons From H1N1 Pandemic Should Be Incorporated into Future Planning" (GAO-11-632).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED, "INFLUENZA PANDEMIC: LESSONS LEARNED
FROM H1N1 SHOULD BE INCORPORATED INTO FUTURE PLANNING" (GAO-11-
632)**

The Department appreciates the opportunity to review and comment on this draft report. We generally concur with the report and support the lessons highlighted in the report.

The forthcoming HHS Retrospective will in fact highlight several of these key themes: the value of planning and preparedness, the necessity of effective communication for a successful response, the importance of timely and accessible information, and deployment planning of the Strategic National Stockpile. Pandemic planning efforts going forward address these and other issues.

Below are a few examples of efforts currently underway to make systems improvements that will aid in pandemic response and the way the Department works with partners and improves capabilities for all threats:

- HHS is leading efforts to align preparedness grants across the Federal government, including the Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) programs, to ensure more consistent administrative requirements. This will have the dual effect of making the process less burdensome to states and grantees and providing a unified Federal message on preparedness.
- The August 2010 Medical Countermeasures Review describes a plan for developing a nimble, flexible capability to produce not only pandemic vaccine but medical countermeasures (MCMs) for any threat. These recommendations are currently being implemented. The Biomedical Advanced Research and Development Authority (BARDA), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), National Institute of Allergy and Infectious Diseases (NIAID) and vaccine industry partners are working together to address manufacturing and product release requirements that will speed availability of vaccines for distribution by up to 4-6 weeks. Also, BARDA awarded two more contracts supporting advanced development of recombinant influenza vaccines towards US licensure. Each of these contracts stipulate US-based manufacturing with the first dose of pandemic influenza vaccine available by 12 weeks post-onset and 50 million doses within 4 months.
- The 2010 President's Council of Advisers on Science and Technology's "Report to the President on Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza" made recommendations on ways to speed the availability of influenza vaccine during a pandemic. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has acted on many of these recommendations. For example, BARDA has issued advanced research and development contracts to several manufacturers developing next-generation recombinant influenza vaccines that may shorten development times considerably, and BARDA, CDC, and the National Institutes of Health (NIH) are working together and with industry to optimize vaccine seed strain production and develop faster approaches to required sterility and

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO)
DRAFT REPORT ENTITLED, "INFLUENZA PANDEMIC: LESSONS LEARNED
FROM H1N1 SHOULD BE INCORPORATED INTO FUTURE PLANNING" (GAO-11-
632)**

potency testing that together could speed availability of vaccines for distribution by up to 4-6 weeks.

- Learning from the challenges related to pandemic vaccine availability estimates early in the 2009 H1N1 response, efforts are underway to improve situational awareness of vaccine production for future events. As mentioned in the report, increased coordination between HHS staff and vaccine manufacturers in November 2009 resulted in improved vaccine availability estimates. HHS is incorporating the need for better communication and coordination into several areas: our planning efforts; between federal officials and vaccine manufacturers to ensure real-time situational awareness for vaccine production and availability; and between federal agencies, states, and local health departments to adequately convey uncertainties in initial vaccine estimates.

Based on experiences from the 2009 H1N1 pandemic and other recent emergencies, such as the Deepwater Horizon Oil Spill and the Haiti Earthquake, the Department recognizes the need to examine and potentially refine how financial resources are made available during an emergency event, and is currently identifying relevant barriers and challenges. Once complete, this analysis should identify additional administrative flexibilities for using federal funds during future emergencies. Additionally, recipients of the Public Health Emergency Preparedness Cooperative Agreement have also been asked to examine their jurisdiction's administrative processes and approaches to receive and use emergency funds to respond to emergency situations in a timely manner, identify relevant barriers, and planned actions to address those challenges.

Appendix IV: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

May 31, 2011

Bernice Steinhardt
Director, Strategic Issues
and
Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Re: Draft Report, GAO-11-632, "INFLUENZA PANDEMIC: Lessons from H1N1 Pandemic Should be Incorporated Into Future Planning"

Dear Ms. Steinhardt and Ms. Crosse:

Thank you for the opportunity to review and comment on this draft report. The U.S. Department of Homeland Security (DHS) appreciates the U.S. Government Accountability Office's work in planning and conducting its review and issuing this report. The Department is pleased to note the report's positive acknowledgment that through interagency planning efforts, federal officials, including DHS, have built relationships that helped facilitate the federal response to the H1N1 pandemic—the first human influenza pandemic in more than four decades.

Although the report does not contain any recommendations specifically directed at DHS, the Department remains committed to continuing to work with the Homeland Security Council, National Security Staff, the Department of Health and Human Services, and other relevant stakeholders to fulfill its shared federal leadership responsibility for pandemic influenza response.

Again, thank you for the opportunity to review and comment on this draft report. Technical comments are being provided under separate cover. We look forward to working with you on future Homeland Security issues.

Sincerely,

A handwritten signature in black ink, appearing to read "John H. Crumpacker".

John H. Crumpacker
Director
Departmental GAO/OIG Liaison Office

Appendix V: Comments from the Department of Labor

U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210



JUN - 6 2011

Ms. Bernice Steinhardt, Director
Strategic Issues
Ms. Marcia Crosse, Director
Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Steinhardt and Ms. Crosse:

Thank you for the opportunity to comment on the Government Accountability Office's (GAO) proposed report, *Influenza Pandemic: Lessons from H1N1 Pandemic Should be Incorporated Into Future Planning*. The Occupational Safety and Health Administration (OSHA) would like to make a few points we believe are important and deserve more attention in the report.

On page 6 of the report, it states that in preparing this report, GAO reviewed documents and interviewed officials from OSHA "regarding guidance on the use of personal protective equipment". This short phrase minimizes OSHA's contribution to the federal pandemic response. In addition to the "guidance on the use of personal protective equipment", GAO could at least add "and the protection of workers' safety and health." OSHA served on the 2009 NSS-created 2009 H1N1 Flu Sub-Interagency Policy Committee and OSHA's draft After-Action Report states that "the full range of OSHA's training, education, enforcement and public outreach programs were used to help employers and workers protect themselves at work during this pandemic."

OSHA appreciates the opportunity to review and respond to GAO's draft report.

Sincerely,

A handwritten signature in black ink, appearing to read "DM".

David Michaels, PhD, MPH

Appendix VI: GAO Contacts and Staff Acknowledgments

GAO Contacts

Bernice Steinhardt, (202) 512-6543 or steinhardtb@gao.gov

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contacts named above, Sarah Veale, Assistant Director; Kim Yamane, Assistant Director; Lori Achman; Mallory Barg Bulman; George Bogart; Helen Desaulniers; Karin Fangman; David Fox; Cathleen Hamann; Seta Hovagimian; and Susan Sato made key contributions to this report.

Related GAO Products

Disaster Response: Criteria for Developing and Validating Effective Response Plans. [GAO-10-969T](#). Washington, D.C.: September 22, 2010.

Influenza Pandemic: Monitoring and Assessing the Status of the National Pandemic Implementation Plan Needs Improvement. [GAO-10-73](#). Washington, D.C.: November 24, 2009.

Influenza Pandemic: Gaps in Pandemic Planning and Preparedness Need to Be Addressed. [GAO-09-909T](#). Washington, D.C.: July 29, 2009.

Influenza Pandemic: Increased Agency Accountability Could Help Protect Federal Employees Serving the Public in the Event of a Pandemic. [GAO-09-404](#). Washington, D.C.: June 12, 2009.

Influenza Pandemic: Continued Focus on the Nation's Planning and Preparedness Efforts Remains Essential. [GAO-09-760T](#). Washington, D.C.: June 3, 2009.

Influenza Pandemic: Sustaining Focus on the Nation's Planning and Preparedness Efforts. [GAO-09-334](#). Washington, D.C.: February 26, 2009.

Influenza Pandemic: HHS Needs to Continue Its Actions and Finalize Guidance for Pharmaceutical Interventions. [GAO-08-671](#). Washington, D.C.: September 30, 2008.

Influenza Pandemic: Federal Agencies Should Continue to Assist States to Address Gaps in Pandemic Planning. [GAO-08-539](#). Washington, D.C.: June 19, 2008.

Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance on Allocating Scarce Medical Resources. [GAO-08-668](#). Washington, D.C.: June 13, 2008.

Influenza Pandemic: Efforts Under Way to Address Constraints on Using Antivirals and Vaccines to Forestall a Pandemic. [GAO-08-92](#). Washington, D.C.: December 21, 2007.

Influenza Pandemic: Opportunities Exist to Address Critical Infrastructure Protection Challenges That Require Federal and Private Sector Coordination. [GAO-08-36](#). Washington, D.C.: October 31, 2007.

Influenza Vaccine: Issues Related to Production, Distribution, and Public Health Messages. [GAO-08-27](#). Washington, D.C.: October 31, 2007.

Influenza Pandemic: Further Efforts Are Needed to Ensure Clearer Federal Leadership Roles and an Effective National Strategy. [GAO-07-781](#). Washington, D.C.: August 14, 2007.

Influenza Pandemic: Efforts to Forestall Onset Are Under Way; Identifying Countries at Greatest Risk Entails Challenges. [GAO-07-604](#). Washington, D.C.: June 20, 2007.

Influenza Pandemic: Applying Lessons Learned from the 2004–05 Influenza Vaccine Shortage. [GAO-06-221T](#). Washington, D.C.: November 4, 2005.

Influenza Vaccine: Shortages in 2004–05 Season Underscore Need for Better Preparation. [GAO-05-984](#). Washington, D.C.: September 30, 2005.

Influenza Pandemic: Challenges in Preparedness and Response. [GAO-05-863T](#). Washington, D.C.: June 30, 2005.

Influenza Pandemic: Challenges Remain in Preparedness. [GAO-05-760T](#). Washington, D.C.: May 26, 2005.

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